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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

JOSE CHUNG LUO, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. SPECTRUM PHARMACEUTICALS, INC., et al., Defendants.	No. 2:21-cv-01612-CDS-BNW CLASS ACTION SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT DEMAND FOR JURY TRIAL

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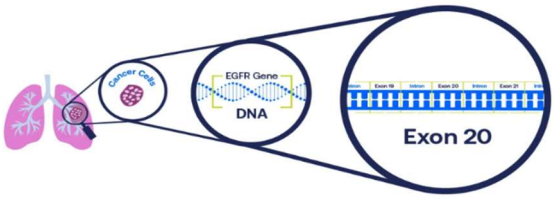
TERM	DEFINITION
AE	Adverse event – side effect caused by treatment
Assertio	Assertio Holdings, Inc. – the company that purchased Spectrum in July 2023
ATM	At-the-market offering – a type of follow-on offering of stock utilized by publicly traded companies in order to raise capital over a relatively short period
BID dosing	Administering a drug two times per day
BLA	Biologics license application – application to FDA for approval to introduce new drug to the U.S. market
Blinded trial	Clinical trial where sponsor does not have access to the data or results until the trial is complete
BTD	Breakthrough therapy designation – expedites the FDA's development and review of drugs)
CEO	Chief Executive Officer
CFO	Chief Financial Officer
Class Period	March 7, 2018 to August 5, 2021
CMC	Chemistry, Manufacturing, and Control – The CMC section of a BLA includes, among other things, a general description of the product's manufacturing and control procedures
CMO	Chief Medical Officer
Cohort 1	Focused on pre-treated patients with a EGFR mutation (ZENITH20 trial)
Cohort 2	Focused on pre-treated patients with a HER2 mutation (ZENITH20 trial)
Cohort 3	Focused on treatment-naïve patients with a EGFR mutation (ZENITH20 trial)
Cohort 4	Focused on treatment-naïve patients with a HER2 mutation (ZENITH20 trial)
Cohort 5	Overflow cohort that includes a mix of patients otherwise qualified for Cohorts 1-4
COO	Chief Operating Officer
CRL	Complete Response Letter – Letter from FDA that acts as a formal denial of a BLA
CTCAE	Common Terminology Criteria for Adverse Events – a set of criteria for the standardized classification of AEs of drugs used in cancer therapy
EDC System	Electronic Data Capture System – the platform Spectrum used to enter and store data and results collected from its clinical trial sites
EGFR	Epidermal Growth Factor Receptor – Enzyme that regulates cell growth, the mutation of which is associated with NSCLC
Exchange Act	Securities and Exchange Act of 1934
Exon	A region of genetic code associated with production of a protein

TERM	DEFINITION
Exon 20	The place where EGFR or HER2 mutate, thus causing NSCLC 
FDA	Food and Drug Administration
FOIA	Freedom of Information Act
Follow-on offering	An issuance of stock after a company's initial public offering
Form 483	FDA letter that details the manufacturing deficiencies observed by inspectors
Hanmi Pharmaceuticals	Company that owned the plant in South Korea that manufactured Rolontis starting in Q4 2018
HER2	Human Epidermal Growth Factor Receptor 2 – Enzyme that regulates cell growth, the mutation of which is associated with NSCLC
MD Anderson	Cancer Center in Houston, Texas
MD Anderson trial	Clinical trial launched in March 2017, sponsored by and solely conducted at the MD Anderson Cancer
Multi-center trial	A clinical trial that occurs in multiple locations
NDA	New Drug Application
Neutropenia	An abnormally low concentration of white blood cells in a patient's blood, which leaves the patient susceptible to infection
NSCLC	Non-Small Cell Lung Cancer
ORR	Objective Response Rate – Common metric for efficacy of cancer treatment that measures the proportion of patients whose tumor either disappears or reduces in size (higher ORR indicates more effective drug)
PDUFA	Prescription Drug User Fee Act – Law passed by Congress in 1992 that governs the new drug approval process by the FDA
PFS	Progression-free survival
Poziotinib/Pozi	An investigational drug that Spectrum claimed limits tumor activity among people with Non-Small Cell Lung Cancer
RECIST 1.1 guidelines	Industry standard for measuring how well a cancer patient responds to treatment
Rolontis	An investigational drug that Spectrum claimed treats a chemotherapy-induced side effect called neutropenia
SEC	Securities and Exchange Commission
Single-center trial	A clinical trial that occurs at one location
SOC	Standard of care
TKI	Tyrosine Kinase Inhibitor – Drug that blocks biological signals,

TERM	DEFINITION
	and can be used to slow or stop tumor progression
Treatment naïve patients	Patients who have never received any cancer treatment
Unmasked trial	Clinical trial where sponsor does have access to the data or results before the trial is complete
ZENITH20 trial	Spectrum's Phase 2, multi-center clinical trial to test Pozi's efficacy and safety for FDA approval, comprised of seven cohorts of patients

This is a class action on behalf of all persons and entities that purchased or otherwise acquired Spectrum Pharmaceuticals, Inc. ("Spectrum" or the "Company") common stock between March 7, 2018 and August 5, 2021, inclusive (the "Class Period"), and were damaged thereby (the "Class"), against: (i) Spectrum; (ii) former CEO Joseph W. Turgeon ("Turgeon"); (iii) former CFO Kurt A. Gustafson ("Gustafson"); (iv) former CMO Francois J. Lebel, M.D. ("Lebel"); and (v) former COO Thomas J. Riga ("Riga") (collectively, "Defendants"), pursuant to §§10(b), 20A and 20(b) of the Securities Exchange Act of 1934 and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. 10b-5).

Lead Plaintiff International Trading Group, Inc. ("Plaintiff"), on behalf of itself and the Class, by and through its counsel Robbins Geller Rudman & Dowd LLP ("Counsel"), alleges the following upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Plaintiff's information and belief are based on, among other things, the independent investigation of Counsel. This investigation includes, but is not limited to, a review and analysis of: (i) Spectrum public filings with the SEC; (ii) public filings and materials concerning Spectrum and its products with the FDA; (iii) transcripts of Spectrum senior management's conferences with investors and analysts; (iv) press releases and media reports issued about and disseminated by the Company; (v) analyst reports issued about Spectrum; (vi) interviews with Spectrum former employees and other relevant witnesses; and (vii) other public information and data regarding the Company.

I. SUMMARY OF THE ACTION

1. Spectrum is a small pharmaceutical company that makes money by purchasing the rights to late-stage developmental drugs with an aim to bring them to market. Spectrum's two primary developmental drugs during the Class Period – and the focus of this pleading – were poziotinib ("Pozi"), a drug that purports to treat specific lung cancers, and Rolontis, a drug that purports to treat neutropenia, a side effect of chemotherapy.

2. As developmental drugs, Pozi and Rolontis did not earn revenue for the Company, and could not earn revenue unless and until they gained FDA approval. Former employees have described the "tremendous pressure" Defendants felt during the Class Period, because "[t]he survival

of the Company depended on the drug[s] getting approved." As a result of this pressure, Defendants attempted to rush the drugs through protracted clinical trials in the hope to gain approval as soon possible. But clinical trials are expensive, and the Company burned $30 million or more per quarter on its trials, quickly depleting the Company's cash stores.

3. With resources dwindling and no way to earn revenue, Defendants sought additional cash through a sale of assets, a public offering, and multiple at-the-market offerings. In a desperate attempt to promote their products and solicit interest for their fundraising efforts, Defendants turned to fraud. They repeatedly materially overstated the status and progress of Pozi and Rolontis, and withheld negative data and results from investors. Defendants' misrepresentations had their intended effect, and Spectrum's stock price traded at artificially high levels. As a former Executive Director from inside Spectrum put it, these representations were misleading because "[i]f you're only reporting positive things, you lead analysts and investors to think the drug is positive and will get approved."

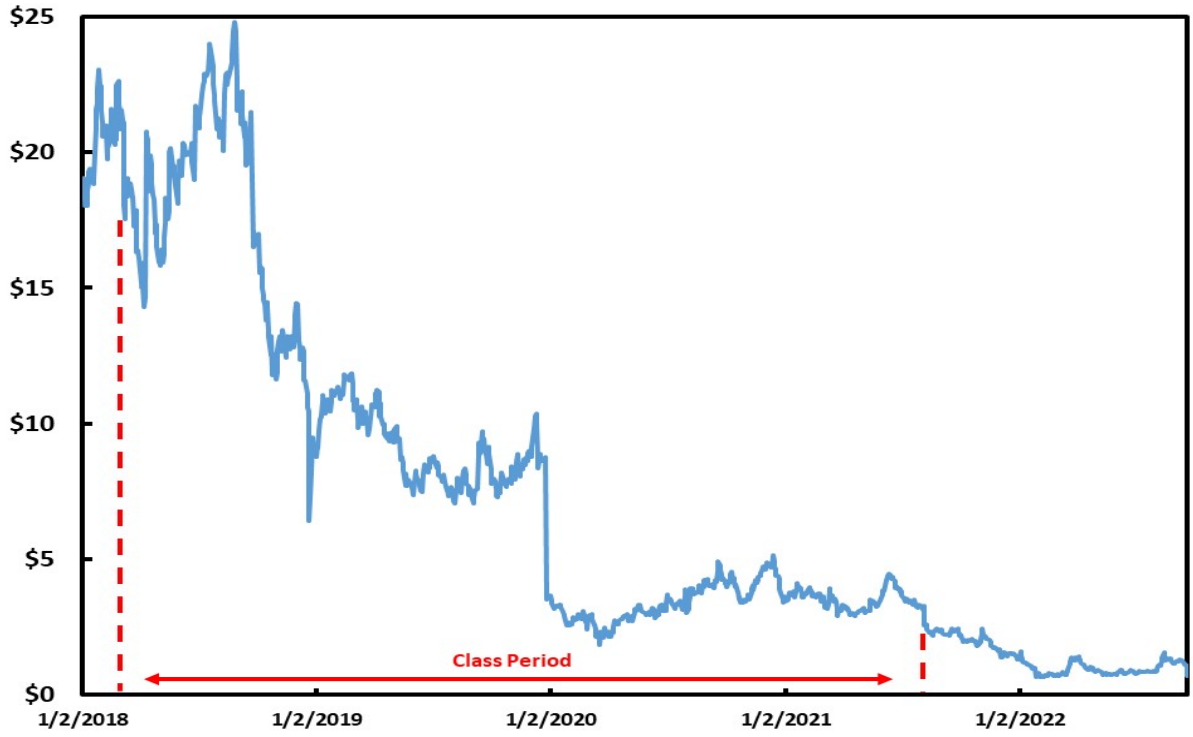
4. Regarding Pozi, Defendants chose to conduct its clinical trial on an "unmasked" basis, meaning they had ready access to the trial data. As the results came in, they unequivocally demonstrated that Pozi was not efficacious or safe enough to warrant FDA approval. Rather than share this adverse information with investors, Defendants concealed it. Instead, they misleadingly cited outdated data and claimed they were "really confident" the FDA would approve the ineffective drug. Defendants also claimed Pozi addressed a "huge unmet need" among lung cancer patients, but misrepresented the then-existing standard of care. Finally, they claimed the side effects of Pozi were "in line" with competing products, when it reality they were so "disabling" and "intolerable" for patients that many were forced to stop treatment before they completed the trial.

5. Regarding Rolontis, Defendants insisted they had taken extreme measures at their South Korean manufacturing facility to ensure they would pass an FDA inspection critical to the drug's approval. They claimed Spectrum was "absolutely ready" for the inspection because the Company had routinely interacted with the FDA to understand its requirements and had retained experts to examine the facility ahead of time. But in reality, according to sources inside the Company but unknown to investors, Spectrum failed its mock inspections multiple times.

Ultimately, Spectrum was so unprepared for the inspection that the FDA found a laundry list of deficiencies, including fundamental mistakes such as failing to properly clean equipment and follow its own protocols.

6. As Defendants misrepresented Spectrum's products to everyday investors, they enriched themselves by dumping their personal shares of Spectrum common stock. For example, just days before announcing that Pozi had failed its clinical trial, and with full knowledge of the deficient results, CEO Joe Turgeon sold nearly half of his shares in two large trades.

7. Defendants' misrepresentations ultimately took their toll on Plaintiff and other investors. By the end of the Class Period, neither Pozi nor Rolontis were approved by the FDA and the price of Spectrum common stock had plummeted from $21.23 to $2.55 per share, a small fraction of its original price. The stock price never recovered from this dramatic decline, ultimately getting delisted at $1.03 per share on July 31, 2023.



II. JURISDICTION AND VENUE

8. The claims asserted herein arise under §§10(b), 20(a), and 20A of the Exchange Act, 15 U.S.C. §§78j(b), 78t(a), and 78t-1, and SEC Rule 10b-5 promulgated thereunder by the 17 C.F.R. §240.10b-5.

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act, 15 U.S.C. §78aa.

10. Venue is proper in this Judicial District pursuant to 28 U.S.C. §1391(b) and §27 of the Exchange Act, 15 U.S.C. §78aa, because Spectrum's headquarters were located within this Judicial District throughout the Class Period, and Defendants conducted substantial economic activity in the Judicial District. As such, substantial acts in furtherance of the alleged fraud have occurred in this Judicial District.

11. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. THE PARTIES

A. Plaintiff

12. Lead Plaintiff International Trading Group, Inc. is a Pennsylvania-based private company owned and operated by its president, John T. McGann, Jr. During the Class Period, Plaintiff made significant investments in Spectrum common stock on the NASDAQ and suffered damages as a result of the violations of the federal securities laws alleged herein, as detailed in the attached certification (Exhibit A). Plaintiff maintains its principal place of business at 151 West Highland Avenue, Suite B, Philadelphia, Pennsylvania, 19118.

B. Defendants

13. Defendant Spectrum was incorporated in Delaware and, during the entire Class Period, its corporate headquarters were in Henderson, Nevada. At all relevant times, Spectrum common stock traded on the NASDAQ under the ticker symbol "SPPI."

14. Defendant Turgeon was Spectrum's President and CEO from December 2017 until December 2021. Prior to becoming CEO, Turgeon was President and COO from April 2014 until December 2017. Spectrum announced Turgeon's retirement on December 1, 2021.

15. Defendant Gustafson was Spectrum's Executive Vice President and CFO from June 2013 until February 2022. Spectrum announced Gustafson's resignation on February 23, 2022.

16. Defendant Lebel was Spectrum's Executive Vice President and CMO from November 5, 2018 until he left on January 4, 2023.

17. Defendant Riga was Spectrum's Chief Commercial Officer from August 2014 to December 2017, then COO from December 2017 to December 2021. Spectrum announced Riga as President and CEO to succeed Turgeon in December 2021, a position he held until Spectrum was acquired by Assertio Holdings, Inc. (Assertio) on July 27, 2023.

18. Turgeon, Gustafson, Lebel, and Riga are collectively referred to hereinafter as the "Individual Defendants." The Individual Defendants, because of their positions at Spectrum, possessed the power and authority to control the contents of Spectrum's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. They were provided with copies of the Company's reports and press releases alleged to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. The Individual Defendants, as senior executive officers of Spectrum and as further detailed herein, were privy to confidential and proprietary information concerning the Company. The Individual Defendants had access to non-public information about the Company's business prospects via access to internal corporate documents, conversations, and connections with other corporate officers and employees, attendance at management and/or Board meetings, and via reports and other information provided to them in connection therewith.

19. The Individual Defendants knew of and/or participated in the fraudulent conduct alleged herein, knew and/or recklessly disregarded that the adverse facts and omissions specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations and omissions that were being made were then materially false and/or misleading.

IV. CONFIDENTIAL WITNESSES

20. Confidential witnesses ("CWs") with direct inside knowledge have provided information demonstrating that: (i) Defendants' Class Period statements were false and misleading; and (ii) Defendants knew or recklessly disregarded the false or misleading nature of their statements. The CWs include individuals formerly employed at Spectrum or related entities during the Class Period, whose accounts corroborate one another and other sources set forth herein. The CWs

provided information on a confidential basis and are particularly described by job description responsibilities, and duration of employment, thereby providing sufficient detail to establish their reliability and personal knowledge. As set forth below, the information provided by the CWs supports a strong inference that Defendants acted with scienter.

A. CW-1

21. CW-1 worked as a Research Coordinator at a clinical lab that participated in Spectrum's ZENITH20 trial of Pozi, which assessed the efficacy and safety of Pozi for patients with Non-Small Cell Lung Cancer (NSCLC). CW-1 worked at the clinical lab from January 2015 until March 2018, and spent most of his/her time on the ZENITH20 trial from its inception until he/she left the lab in March 2018.

22. ***Treatment and Assessment of Patients***. At the clinic, CW-1 was responsible for interacting directly with patients who participated in the study. CW-1 assisted with recruitment, guided patients through assessments and treatments, interviewed patients concerning their experiences and side effects, and input patient data. For recruitment, CW-1 screened patients to see if they qualified to participate in the ZENITH20 trial. To qualify, among other things, patients at CW-1's clinical lab had to have: (1) "measurable disease" based on an MRI (magnetic resonance imaging, used to form pictures of the anatomy and the physiological processes inside the body) or CT scan (computed tomography scan, used to obtain detailed internal images of the body); (2) a genetic mutation at EGFR (epidermal growth factor receptor); and (3) a failed attempt at first-line chemotherapy treatment (*i.e.* they could not be treatment naïve).[1]

23. Physical assessments and treatments were primarily conducted by the Principal Investigator, a doctor at the clinic, but CW-1 helped guide patients through the process and assisted the Principal Investigator with in-person assessments and treatments. The ZENITH20 trial involved assessing patients and administering Pozi in cycles. There was a particular protocol for each day of treatment: Cycle 1, Day 1; Cycle 1, Day 15, and so on. Based on this protocol, CW-1 helped make clinical assessments of each patient at specified intervals.

[1] CW-1 could not say which cohorts he/she worked on within the ZENITH20 trial, but the timing and exclusion criteria indicate that he/she worked with patients in Cohort 1.

24. The assessments included radiologic scans, which were read by a radiologist. The radiologist's interpretation of a scan included performing measurements of a patient's tumor, assessing "the response or progression of" the NSCLC tumors over time, and issuing reports that made conclusions about the responsiveness of Pozi for each patient. The measurements included comparing the size of the tumor(s) on the particular day of the scan with size of the tumor on the Day 1 scan. The radiologist also looked for additional tumors. Thus, there could be a reduction in the growth of Tumor 1, for example, but there could be "new or additional" tumors that developed at the same time that Tumor 1 shrank. Accordingly, a patient's disease could progress on an overall basis even though some tumors shrank. The Principal Investigator "signed off" on the scan reports from the radiologist.

25. The tumor measurements followed the RECIST 1.1 guidelines, which concerned "measurable and non-measurable disease" in the context of pharmaceutical trials. CW-1 explained that Spectrum, and not the clinic, chose to use the RECIST 1.1 guidelines "at the outset of the trial." The RECIST 1.1 guidelines dictated whether a patient's response to Pozi was classified as a complete response (cancer disappears), partial response (cancer load shrinks), or non-response (cancers progresses or stays the same). CW-1 explained that it took 3-4 days from the time of the scan to determine the responsiveness of the patient to the drug.

26. ***Data Shared with Spectrum***. CW-1 explained that data collected from each patient included scans, tumor response (including the final determination of a patient's response to the drug), measurements of the tumors, lab work, adverse effects, and "everything we collected in the regular course of business." The data was recorded in three ways: (1) internal charts used by the blood specialist; (2) physical pieces of paper; and (3) on the EDC (electronic data capture) system. CW-1 helped transpose and upload all of the information in a patient's chart to the EDC system.

27. The information was typically uploaded within one week of being collected. Spectrum controlled the EDC system and had access to the information stored on it in real time. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call him/her on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that

the calls happened "throughout the trial." CW-1 added that he/she was "pretty sure that higher-level people could see it" as he/she was not aware of any restrictions that prevented executives from accessing the database.

28. CW-1 also attended weekly telephonic meetings with a "core group" of Spectrum personnel to discuss data from the ZENITH20 trial. Spectrum employees who attended the weekly calls included Senior Vice President of Clinical Research Dr. Zane Yang,[2] Executive Director of Operations and Medical Development Rocky Washington, Director of Clinical Operations Sanjay Mourya, and Clinical Research Associate Olena Golanska. The weekly calls were "always the same. It was very regimented." Before the meetings, Spectrum would send calendar invites with an agenda, and then Spectrum "took meeting minutes" internally. On each call, CW-1 "went over every patient on the study" who was at his/her clinical site. CW-1 shared with Spectrum, among other things, "the results of each scan, the toxicity and adverse events" for each patient.

29. CW-1 further recalled that once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient." The Spectrum representative, usually Clinical Research Associate Olena Golanska, carefully compared each data point in the binder with the data that had been entered into the EDC to make sure the two data sets were consistent. According to CW-1, the Spectrum "rep" then took the data and "reported the information up the chain" at Spectrum.

30. CW-1 said he/she was never made aware that there was an Independent Data Review Committee ("IDRC") that reviewed the data, noting that he/she always spoke directly to Spectrum personnel about the data collected at his/her clinical site. He/she explained that all of the individuals who called him/her to ask about the data from his trial were Spectrum employees.

31. ***Adverse Events***. CW-1 recalled that "toxicity levels were tough" and that toxicity was the biggest issue for patients taking Pozi. Spectrum (and therefore CW-1's clinic) adhered to the CTCAE (Common Terminology Criteria for Adverse Events), a professional standard that classifies AEs (adverse events) in terms of severity. Patients suffered side effects from Pozi that

[2] In his position as Senior Vice President of Clinical Research, Dr. Yang reported directly to Lebel.

made them extremely uncomfortable, such as severe diarrhea and facial rashes. CW-1 reported that the intolerable side effects impacted the effectiveness of the drug, because "the longer patients could tolerate the side effects, the better they did." According to CW-1, the main objective with each patient in the ZENITH20 trial was to "keep them on the drug for the longest time at the highest dose possible." CW-1 said it was his/her understanding that Pozi failed because of "toxicity and the AEs. If the AEs had been managed better by the sites, they would have had better outcomes."

32. CW-1 and the Principal Investigator sought to mitigate the adverse effects by developing their "own protocol" for managing the side effects. The protocol included early administration of steroids and antibiotics, using "magic mouthwash" and even "butt paste." Despite these efforts, CW-1's clinic was forced to do "dose reductions" and "drop outs" for several patients. CW-1 recalled that "every patient was dose-reduced eventually." Patients dropped out due to "a new lesion," a tumor that grew "bigger rather than smaller," or "undesirable side effects or hospitalization." In any of those cases, the patient "went off study," meaning that they stopped taking Pozi and the clinic stopped recording data.

33. CW-1 also recounted that, on his/her weekly meetings with Spectrum, they discussed the results of other clinical sites. CW-1 learned that "other sites had trouble keeping people on the trial" due to AEs. CW-1 got the impression that his/her clinic was more successful on a relative basis. CW-1 learned through "nonchalant conversations" with Spectrum that "other sites didn't manage the side effects" as well, and that patients who could not tolerate the side effects were dropping out of the ZENITH20 trial.

34. CW-1 added that a weekly newsletter was sent out to "all the sites" participating in the ZENITH20 trial. CW-1 recalls that the newsletter included enrollment numbers and, according to his/her best recollection, information about "AEs and efficacy."

35. ***Open Trials***. CW-1 confirmed that ZENITH20 was an open-label trial. He/she also expressed his/her opinion that open trials like ZENITH20 were easier in the end because blinded trials included restrictions on communications with the Company, which he/she did not have with ZENITH20. According to CW-1, open trials provide more "transparency" between the trial sites and the Company.

B. CW-2

36. CW-2 worked as an Executive Director at Spectrum from the second quarter of 2019 until the third quarter of 2020. In this role, he/she spoke regularly with principal investigators and healthcare professionals at the trial sites for ZENITH20, and assisted with "mitigating the side effects" patients experienced during that trial. CW-2 reported directly to Lebel during his/her time at Spectrum and spoke with Lebel on a regular basis.

37. ***Spectrum Knew the Targets and Had Access to the Data***. CW-2 explained that, ahead of the ZENITH20 trial, Spectrum executives and the FDA determined the target ORR endpoints that Pozi would need to hit in each cohort to support FDA approval. CW-2 said that Spectrum knew "the rules of the game, before the trial start[ed]." CW-2 also said that target ORRs are "based on existing therapies," and that Spectrum knew which existing treatment Pozi would be compared to when setting the ORR endpoint.

38. CW-2 also said that Spectrum used an EDC system that contained data and results collected from the clinical sites, including "efficacy graphs and safety printouts." The data stored on the EDC was available to Spectrum personnel throughout ZENITH20.

39. ***Adverse Events***. Lebel made CW-2 the "point person to manage the side effects from Poziotinib," which involved speaking to the doctors and nurses at the clinical trial sites. CW-2 recalls that AEs were a major issue during the ZENITH20 trials, because the "16-milligram-per-day dose was far higher than what was needed, and it corresponded with bad side effects." CW-2 remembers that "85 percent of patients had serious side effects" such as rashes and diarrhea, and the AEs "were disabling, intolerable." Many patients who wanted to continue with the drug had to stop because the AEs were so severe. CW-2 explained that patients dropping off the medication had two negative effects: first, there were patients "suffering" from the AEs, and second, "it affected the efficacy of the drug if patients dropped out." Similarly, trial clinicians "could hold the dose [at the same level] or lower it temporarily, but if they lowered the dose, they would not be getting the efficacy." CW-2 recalled being torn "between treating the patients and doing the right thing for the company."

40. Knowing patients were dealing with the AEs due to Lebel's decision to administer too much of the drug made CW-2's job stressful, and he/she is "completely embarrassed" about how the ZENITH20 trial was run.

41. ***Lebel Was in the Loop***. By the time CW-2 started at Spectrum, Lebel already knew that "the Pozi dose was too high" for patients to tolerate. Lebel described his concern about the high dosage "in several meetings with other people there," including CW-2. CW-2 recalls that Lebel "said crystal clear that the dose was too high. But he wouldn't do a new PK study – a pharmacokinetic study" to trial a lower dose of Pozi "because that would slow the whole program down." CW-2 explained that in FDA trials, "you must prove to the FDA that [a compound] is efficacious and safe." "Efficacy and safety are a teeter-totter. A drug with a higher efficacy can have a high AE profile."

42. ***Trial Design***. CW-2 acknowledged that safety and efficacy results were better for the MD Anderson trial than for the ZENITH20 trial, but noted that such a result was expected because ZENITH20 was larger and more geographically dispersed. Accordingly, "[y]ou expect lower results because you have sites differing from other sites." Single-site studies like the MD Anderson trial, in contrast, produce "sloppier results" because healthcare providers in such circumstances can have "unconscious biases" or incentives to "minimize, delay or not report AEs" in order to keep patients on the drug for a longer period of time. In large formal trials like ZENITH20, "you have to stick to the dose. You can't go below" the prescribed dose in the protocol for that trial.

43. CW-2 also said that blinded trials had more restrictions than open trials regarding who at the Company had access to data. CW-2 confirmed that ZENITH20 was an open trial.

44. ***Hanmi Factory***. CW-2 described Rolontis as "trivial" and a "me-too to Neulasta."[3] CW-2 further explained that, although Spectrum wanted to supervise procedures at the Rolontis factory in South Korea, in reality Spectrum did not have control over what happened at Hanmi. CW-2 recalls that Spectrum executives "sent inspectors to Hanmi to do mock inspections," but Hanmi "failed [the mock inspections] a couple of times." This is because "the quality of plants and people

[3] Neulasta also treats neutropenia, and was already on the market.

[at Hanmi] were not up to industry standards." CW-2 said it was "common knowledge" at Spectrum that Hanmi failed its mock inspections, and that he/she found out about them "in the hallway and in meetings." The FDA requires pharmaceutical manufacturers to follow "Good Laboratory Practice," which is a set of FDA rules that are very specific. CW-2 explained that FDA inspections are focused on documentation, and that Hanmi's "records and documentation was the problem."

45. ***Company Culture***. CW-2 said working at Spectrum was "like the army," as the c-suite's (executive-level managers) approach to lower-level management was, "do what you're told. Your manager is god." CW-2 described Lebel, his boss, as "very controlling," noting that the understanding among his peers was "don't question Francois."

46. CW-2 also recalls that management was under "tremendous pressure" during his/her tenure to get a drug approved. He/she said Spectrum's "senior leadership was struggling to maintain the confidence of the Board. They [would] do anything to get a drug to market" because the Company needed new lines of revenue. CW-2 explained: "The survival of the Company depended on the drug [Pozi] getting approved." CW-2 described his boss, Lebel, as a "businessman physician" who understood that pressure.

47. As a result of this pressure, Spectrum was "selective about what it shared with the market." CW-2 explained that "companies present things in the best possible light and commit errors of omission." As an example, he/she said Spectrum "didn't mention about the side effects and the dosage issues. If you're only reporting positive things, you lead analysts and investors to think the drug is positive and will get approved." He/she said this was a misleading impression, because "[i]t was the understanding when I left [in Q3 2020]" within Spectrum that Pozi would not be approved by the FDA due to the intolerable side effects and their impact on efficacy.

V. FACTUAL ALLEGATIONS

A. Background on Spectrum

48. At all relevant times during the Class Period, Spectrum was a relatively small company with less than 250 employees. Spectrum kept its corporate headquarters in Henderson, Nevada, and maintained a research facility in Irvine, California, but outsourced most of its manufacturing overseas to South Korea.

49. According to its website, Spectrum was "a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted drug products." Spectrum did not create drugs, but rather purchased drugs in late-stage clinical trials with an aim to bring them to market and profit off them. Spectrum focused on hematologic (blood) and oncologic (cancer) drugs. During the Class Period, Spectrum focused on two developmental drugs, Pozi and Rolontis.[4]

B. Spectrum's Cash Spend

50. Spectrum spent millions of dollars in its pursuit to obtain FDA approval for Pozi and Rolontis, in order to break into the drug market as fast as possible. Throughout the Class Period, Gustafson updated investors on the Company's "cash burn," meaning the amount of money the Company consumed in a quarter. At the same time, Spectrum monitored its total cash available before it ran out of money completely, which it called the Company's "cash runway." As Spectrum endured lengthy clinical trials for its two main products, Pozi and Rolontis, its cash on hand dwindled. The following chart shows the cash burn and cash runway Defendants reported on Spectrum's conference calls and SEC filings throughout the Class Period.[5]

Quarter	Cash Burn	Cash Runway
Q1 2018	$45 million	$184 million
Q2 2018	$9.1 million	$174 million
Q3 2018	$8 million	$167 million
Q4 2018	$9.1 million	$157.5 million
Q1 2019	~ $30 million	$272.6 million
Q2 2019	~ $30 million	$118 million
Q3 2019	~ $30 million[6]	$124.6 million
Q4 2019	$28 million	$64.4 million
Q1 2020	$33 million	$70.3 million

[4] On March 17, 2022, Spectrum announced that, due to a naming conflict identified by the FDA, it would no longer use the name "Rolontis," but would instead refer to the drug by its scientific name, "eflapegrastim." The drug was subsequently rebranded with the name "Rolvedon." For clarity, and because Spectrum used "Rolontis" throughout the Class Period, Plaintiff will refer to the drug exclusively as Rolontis in this pleading.

[5] As used herein, "Q" means the Company's fiscal quarter (*e.g.*, Q1 2020 means the first fiscal quarter of the Company's fiscal year 2020).

[6] Spectrum did not provide quarterly cash burn disclosures for Q1 2019, Q2 2019, or Q3 2019. The numbers included in the chart are based on Gustafson's statement on February 27, 2020 that "we burned $28 million in the quarter [Q4 2019]. If you take a look at the last couple of quarters, we're in that sort of $30 million range."

Quarter	Cash Burn	Cash Runway
Q2 2020	$27 million	$85.1 million
Q3 2020	$28 million	$77.1 million
Q4 2020	$33 million	$46 million
Q1 2021	$34.5 million	$69.5 million
Q2 2021	$29.7 million	$114.6 million

51. The Company financed its prolific spending in three ways. First, in January 2019, Spectrum announced it had entered into an agreement to sell its portfolio of seven FDA-approved hematology/oncology products to Acrotech Biopharma for $160 million. The deal unloaded all of Spectrum's assets other than Pozi and Rolontis, and its only sources of earning revenue to expand its cash runway. On a conference call held on January 17, 2019, Turgeon told investors, "the proceeds generated by the sale will significantly strengthen the financial position of the company, providing the capital needed to develop our 2 late-stage pipeline assets, pozitinib and ROLONTIS, and placing us in a solid position to evaluate additional growth opportunities."

52. Second, Defendants initiated three ATM (at-the-market) offerings to raise additional money from the investing public, which were open from April 5, 2019 to March 2, 2020, May 8, 2020 to June 30, 2020, and November 6, 2020 through the end of the Class Period. ATM offerings are "follow-on offerings" of stock utilized by publicly traded companies in order to raise capital over a relatively short period.[7] In an ATM offering, the issuer places newly issued shares into the market incrementally through broker-dealers at market prices. A higher market price means a greater amount of money per share for the issuing company. ATM offerings allow the issuing company to raise capital on an as-needed basis with the option to refrain from offering shares if the market price on a particular day is unsatisfactory. In other words, an issuing company may start and stop an ATM offering at any point, selling more shares and raising more money when there is an opportunity in the market. ATM offerings are subject to the anti-fraud provision under §11 of the Securities Act of 1933, which imposes strict liability on the makers of registration statements.

53. In each of Spectrum's ATM offering prospectuses, Defendants said the money from the offerings would be used for "general corporate purposes, including, without limitation, research

[7] A "follow-on offering" is a public offering of stock that occurs after the company's initial public offering.

and development and clinical development costs to support the advancement of our in-development drug candidates, activities in connection with the launch of our in-development drug candidates." The ATM offerings ultimately had their intended effect: by the end of 2021, Spectrum raised $52.6 million of proceeds pursuant to their ATM offerings.

54. Third, before the market opened on July 30, 2020, Spectrum announced the pricing of an underwritten public offering of 21,666,667 shares of common stock at a public offering price of $3.00 per share, a discount off the prior day's closing price of $3.88 per share. The $3.00 offering price was nonetheless inflated by Defendants' fraud, as by early July 2020, Defendants had access to the Cohort 3 results, indicating that the cohort did not meet its primary endpoint. This financial machination also had its intended effect: the Company reaped approximately $61.1 million in net proceeds from the offering.

C. Process for FDA Approval

1. Purpose of FDA Approval Process

55. Before a sponsoring company can market and commercially sell its drug in the United States, the FDA requires the company to put its drug through pre-clinical (animal) trials and clinical trials that involve three phases of human testing (*i.e.*, Phases 1 through 3, discussed in detail below). When the FDA approves a drug, it means the agency has determined that the drug is safe and effective for its intended use and the benefits of the drug outweigh its risks when used according to its approved labeling. According to Vivek Subbiah, M.D., a prominent oncology physician and researcher at MD Anderson, "[i]f something's been approved by the FDA, you can trust that it's safe."

2. General Structure and Sequence of Clinical Trials

56. A drug must demonstrate efficacy and safety through three phases of clinical trials conducted in human patients before it may be submitted to the FDA for approval. Drugs that fail to demonstrate the requisite safety or efficacy at an earlier phase cannot move on to later phases.

- *Phase 1 Clinical Trials*: This is the first time the sponsoring company's drug will be given to humans. These trials typically involve small numbers of healthy volunteers or patients and determine the best dose and preliminary safety data. According to the

American Cancer Society: "Phase I studies are done to find the highest dose of the new treatment that can be given safely without causing severe side effects."

- *Phase 2 Clinical Trials*: In Phase 2 clinical trials, controlled studies of usually 25-100 human patients with the targeted disease are treated using the dose and method found to be the safest and most effective from the Phase 1 study. Larger numbers of patients get the treatment in Phase 2 trials, so less common side effects may be seen. Phase 2 is the first opportunity to assess the drug's efficacy and safety, which will be tested more rigorously in Phase 3.

- *Phase 3 Clinical Trials*: This Phase usually involves a larger number of patients with the targeted disease. Investigators (typically physicians) monitor the patients to determine the drug candidate's efficacy and to observe and report any adverse reactions that may result from long-term use of the drug on a large, more widespread, patient population. During Phase 3 clinical trials, the drug candidate is typically compared to either a placebo or a standard treatment for the target disease in a randomized trial where some patients are treated with the drug candidate, and some are treated with a placebo or a standard treatment.

57. In order to support FDA approval in terms of efficacy, the clinical trials must demonstrate to the FDA that the drug provides a "clinically meaningful" benefit over existing therapies.

3. Applying for FDA Approval: Breakthrough Therapy Designation

58. Once the clinical trials conclude, the sponsoring company will meet with the FDA to discuss submission of a NDA (New Drug Application). Alternatively, a sponsoring company may apply for expedited development and review of their drug through a fast track designation, called breakthrough therapy designation (BTD).

59. A drug qualifies for BTD only if the FDA determines it: (1) treats a serious condition; and (2) represents a "substantial improvement" over existing therapies. According to the FDA:

> The determination of whether the improvement over available therapy is substantial is a matter of judgment and depends on both the magnitude of the drug's effect on a clinically significant endpoint (which could include duration of the effect) and the importance of the observed effect to the treatment of the serious condition or serious aspect of the condition.

60. When other therapies exist in the market, the "substantial improvement" standard represents a higher bar than the "clinically meaningful" standard considered for FDA approval.

Because the FDA will consider preliminary clinical evidence when reviewing BTD applications, evidence is typically in the form of Phase 1 or Phase 2 trial data.

61. A drug that receives BTD status is eligible for "fast track" designation features such as more frequent meetings with the FDA, intensive guidance for a drug development program, and organizational commitment from the FDA involving senior managers. Once an applicant submits its BTD request, the FDA will respond within 60 days of receipt.

4. Biologics License Application

62. The final step before FDA approval is submitting a biologics license application (BLA) with the agency, which includes a mandatory manufacturing facility inspection. A BLA is a request for permission to introduce a biologic product into interstate commerce.[8] BLAs provide documentation, including clinical trial data and other information, that demonstrates the safety and efficacy of the drug to show it is safe and ready for market.

63. BLAs are organized into five modules. Module 1 is country or region specific and contains the information that is unique to a region. Module 2 contains summary documents for Modules 3-5. Module 3 is called the Quality Module and contains all of the chemistry, manufacturing, and control (CMC) information for the new product, which includes safety and efficiency data. In addition, the CMC section of an application includes, among other things, a general description of the product's manufacturing and control procedures. As an important part of Module 3, the FDA will inspect the manufacturing facility to ensure that the manufacturers are making biological drug products that meet the conditions of licensure noted in the BLA. During these inspections, the FDA must "verify that all relevant data were submitted to the BLA or supplement, and data are accurate and complete," and "review product process, process controls, analytical testing, and process validation for the drug substance and drug product." In other words, the FDA verifies the representations the applicant made in various sections in the BLA, including

[8] FDA, *Biologics License Applications (BLA) Process (CBER)* (Jan. 27, 2021), https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber.

facility information, equipment information, and batch records. Finally, nonclinical data are found in Module 4, and clinical data are presented in Module 5.

64. Pursuant to the Prescription Drug User Fee Act (PDUFA), the FDA has 60 days to decide if the BLA is complete and acceptable for full review. If accepted, the FDA then has 10 months to respond with an approval or non-approval. This crucial deadline in the BLA process is commonly referred to as the "PDUFA date." While the applicant awaits its PDUFA date, the applicant and the FDA can communicate with each other to set expectations and address concerns. This communication can come in the form of correspondence, meetings, and phone calls between the applicant and the agency.

65. In the event of a non-approval, the FDA issues a responsive document called a Form 483 that details the manufacturing deficiencies observed by inspectors and then a complete response letter (CRL) which acts as a formal denial of the BLA.

5. Open Trial vs. Blinded Trial

66. Clinical trials can be conducted on either a blind basis, which means that the company does not have access to the data and results until the trial is complete, or an unmasked or "open-label" basis, which means the data is available throughout the trial to subjects, physicians, and the sponsor company. It is widely understood that blinded trials are more likely to mitigate the effects of bias in clinical trials than unmasked trials. According to *Guidance for Industry*, E9 Statistical Principles for Clinical Trials, published by the FDA in September 1998, conducting a blind trial is one of "[t]he most important design techniques for avoiding bias in clinical trials." The *Guidance for Industry* explains that blinding a trial prevents intentional or unintentional manipulation of data, specifically:

> Blinding or masking is ***intended to limit the occurrence of conscious and unconscious bias*** in the conduct and interpretation of a clinical trial arising from the influence that the knowledge of treatment may have on the recruitment and allocation of subjects, their subsequent care, the attitudes of subjects to the treatments, the assessment of end-points, the handling of withdrawals, the exclusion of data from analysis, and so on. The essential aim is to prevent identification of the treatments until all such opportunities for bias have passed.

67. Karen Higgins and Gregory Levin, statisticians at the FDA's Office of Biostatistics, have similarly cautioned, "[k]nowledge of comparative summary-level interim outcome results by subjects, investigators, the sponsor, or the public can negatively impact trial conduct (*e.g.*, recruitment, adherence, and retention) and impair ultimate interpretation of results." They added, "[t]he most important point is to conduct a fully blinded trial whenever at all feasible."

68. Despite the potential bias created by open-label trials, pharmaceutical companies that pay for the trials can unilaterally decide whether to look at the data. As the Pharmaceutical Research and Manufacturers of America, put it: "As owners of the study database, sponsors have discretion to determine who will have access to the database."

6. Single-Center vs. Multi-Center Trials

69. Trials that occur at a single clinic are typically regarded as less reliable and more susceptible to bias than trials that occur across multiple clinics. According to *Guidance for Industry* from the FDA, multicenter trials lead to more translatable results:

> [A] trial may be designed as a multicenter (and multi-investigator) trial primarily to provide a better basis for the subsequent generalization of its findings. This arises from the possibility of recruiting the subjects from a wider population and of administering the medication in a broader range of clinical settings, thus presenting an experimental situation that is more typical of future use.

70. In other words, since multicenter trials by definition involve a more diverse and representative pool of treatment centers across the country and the world, results from multicenter trials are more reliable in predicting how a drug will perform in real life. An article titled: "Why we should be wary of single-center trials," published in *Critical Care Medicine* similarly found that "[m]any positive single-center trials have been contradicted when tested in other settings." According to CW-2, single-site studies produce "sloppier results" because healthcare providers in such circumstances can have "unconscious biases they're not aware of." The physician running an independent trial may "minimize, delay or not report AEs" in order to keep patients on the drug being studied for a longer period of time.

D. Pozi Clinical Trials

1. The Drug Candidate

71. Pozi is an investigational drug that Spectrum hoped would limit tumor activity among people with certain types of lung cancer. Lung cancer is generally divided into two major subtypes: NSCLC and Small Cell Lung Cancer. NSCLC makes up 85% of all cases of lung cancer, and can be further classified by the particular genetic mutations that lead to abnormal cell growth, causing tumor formation and progression. Spectrum claims that Pozi was designed to treat two specific genetic mutations associated with NSCLC: (1) mutations at exon 20 of the epidermal growth factor receptor (EGFR) and (2) mutations at exon 20 of the human epidermal growth factor receptor 2 (HER2).[9] To treat cell growth caused by such mutations, patients take drugs called "inhibitors" designed to stop or slow cell growth through various mechanisms. Pozi was designed as a tyrosine kinase inhibitor (TKI), which is a class of inhibitors that work by blocking enzymes that promote cell growth.

72. Between EGFR mutations and HER2 mutations, EGFR is much more prevalent in the populations studied as of 2018. It was: four fold more common in the U.S. (16,300 vs 3,900 cases); four fold more common in Europe (28,000 vs 6,700 cases); and fifteen fold more common in Japan (29,100 vs. 2,100 cases).

73. At the start of the Class Period, another TKI called Tagrisso existed in the market to treat patients with NSCLC derived from EGFR mutations (although they were not specific to exon 20 mutations). The side effects of Tagrisso are moderate, with 18% of patients experiencing serious side effects and 2.9% requiring a dose reduction.

2. Measurements of Efficacy and Safety

74. The efficacies of cancer treatments are measured in terms of ORR (objective response rate). ORR measures the proportion of patients for whom the trace of cancer either disappears or reduces in size. Therefore, a higher ORR indicates a more effective drug.

[9] An "exon" is a region of genetic code associated with production of a protein. EGFR and HER2 are proteins (or more specifically, enzymes) that regulate cell growth. Accordingly, "exon 20" refers to the position on the protein structure where the mutation is located.

75. The RECIST 1.1 guidelines from the *European Journal of Cancer* represent the industry standard for measuring how well a cancer patient responds to treatment and ORR. According to the RECIST guidelines, patients receive a preliminary radiological scan before treatment to assess baseline tumor size. Then, after a set duration of treatment, patients receive the first treatment-related scan, which is evaluated to determine whether the tumor(s) responded to the medication, and whether new tumors have appeared. After another set duration of treatment, confirmatory scans are performed and analyzed for tumor progression.

76. Based on these scans, each patient is assigned to one of the following categories based on their response to the medication:

- ***Complete Response***: Disappearance of all tumors assessed;
- ***Partial Response***: Decrease in sum diameter of tumors assessed;
- ***Progressive Disease:*** Increase in sum diameter of tumors assessed;
- ***Stable Disease***: Insignificant increase or decrease in sum diameter of tumors assessed; or
- ***Invaluable Response***: Course of measurements not completed. This could be for a variety of reasons, including, for example, "death" or "tumor assessments not repeated."

77. The ORR of the population is simply the percentage of total patients who fell into the "Complete Response" or "Partial Response" categories. The RECIST 1.1 guidelines suggest, but do not require, assessments from the drug sponsor: "For trials where objective response (CR + PR) is the primary endpoint . . . it is recommended that all claimed responses be reviewed by an expert(s) independent of the study."

78. At the time of the Pozi trials, the best existing therapy for patients with NSCLC was chemotherapy combined with a vascular endothelial growth factor ("VEGF") inhibitor, which achieved an ORR of 22.9%. But drugs other than Pozi were also in development, some of which have since entered the market with higher efficacies. On May 21, 2021, the FDA approved Rybrevant, which demonstrated an ORR of 40% among patients with EGFR exon 20 mutations.

And on August 5, 2022, the FDA approved Enhertu, which demonstrated an ORR of over 50% among patients with HER2 exon 20 mutations.

79. The safety of cancer drugs is assessed according to the number and severity of patients who suffer AEs as a result of the drug. The CTCAE are a set of criteria for the standardized classification of AEs of drugs used in cancer therapy. The CTCAE system is a product of the U.S. National Cancer Institute. The CTCAE classifies AEs in terms of symptom and severity: grade 1 is the least severe and grade 5 is death. The CTCAE also indicates how a particular symptom of an AE should be mitigated, depending on its grade.

3. MD Anderson Trial

80. In March 2017, MD Anderson launched a Phase 2 open-label clinical trial of Pozi with the assistance of Spectrum. Patients received their baseline scan, an initial scan after 8 weeks of treatment with Pozi, and then a confirmatory scan after 16 weeks. Accordingly, fully confirmed data was available for each patient after 16 weeks of treatment at MD Anderson. Spectrum did not announce final results until September 24, 2018. The MD Anderson trial assessed the efficacy of a 16 mg QID dose of Pozi at treating patients with NSCLC with dose reductions to 12 or 8 mg allowed, separately evaluating its treatment of EGFR and HER2 mutations. The study had 80 total participants, 50 of whom had an EGFR mutation and 30 of whom had a HER2 mutation. Every participant received treatment at the MD Anderson Cancer Center in Houston, Texas. MD Anderson has long been rated by *US News* as the best hospital for cancer care in the nation, ranking as one of the top two hospitals for cancer care every year since the survey began in 1990.

81. Spectrum intended to use data from the MD Anderson trial to apply for BTD status, which would entitle Spectrum to expedited consideration of its FDA approval application. Spectrum could not obtain FDA approval with the MD Anderson data alone, so, whether or not Pozi achieved BTD status, Spectrum intended to collect more comprehensive data in a separate, multi-center trial.

4. ZENITH20 Trial

82. Spectrum initiated the ZENITH20 trial, the comprehensive Phase-2 study of Pozi, in October 2017. Defendants planned to use data from the ZENITH20 trial to get FDA approval for the drug. ZENITH20 included 603 participants, of which 87 were in Cohort 1, and 70 were in Cohort 3.

Participants in the ZENITH20 trial were evaluated sooner than participants in the MD Anderson trial, receiving initial scans at 4 weeks instead of 8, and confirmatory scans at 8 weeks instead of 16. As a result, fully confirmed data was available for patients just 8 weeks after treatment began. Spectrum began enrolling patients for Cohort 1 from the outset of the ZENITH20 trial, and enrollment for Cohort 3 began on May 9, 2019.

83. As originally submitted to the FDA in October 2017, the ZENITH20 trial was split into two cohorts of different patients. Both cohorts focused on patients who had been previously treated with other cancer drugs: Cohort 1 focused on patients with an EGFR mutation, and Cohort 2 focused on patients with a HER2 mutation. Both cohorts received a 16 mg dose of Pozi once per day. In September 2018, Spectrum expanded the study to add Cohort 3 and Cohort 4, which would also receive 16 mg of Pozi once per day. Both new cohorts included treatment naïve patients, meaning patients who had never received any cancer treatment. Cohort 3 focused on EGFR patients and Cohort 4 focused on HER2 patients. The FDA generally holds drugs to a higher standard in treatment-naïve populations because the patients are generally healthier and more receptive to treatment.

84. On July 22, 2019, Spectrum announced an expansion of the ZENITH20 trial, adding three additional cohorts to the study. Among these three new cohorts was Cohort 5, which Defendants described to the public as an overflow cohort to treat "[p]atients who meet the criteria for enrollment in Cohort 1 to 4, but the enrollment in the respective cohort has been closed." Spectrum used Cohort 5 to explore a new dosing regimen. On August 8, 2019, Lebel announced that for patients in Cohort 5, dosing would be randomized between 10 mg, 12 mg, and 16 mg per day. Additionally, Spectrum would allow patients in Cohort 5 who started on a lower dose to potentially escalate to a higher dose if they showed signs of disease progression. Defendants acknowledged that the additional patients "will give us additional data that is always useful for any drug. When you go to market, the more data you have, the better it is." Cohort 6 included NSCLC patients whose tumor(s) progressed while on treatment with first-line osimertinib. Cohort 7 included NSCLC patients with a variety of less common mutations.

85. Unlike the MD Anderson trial, the ZENITH20 trial was conducted at 64 different medical centers within and outside the United States, including locations in Europe, Canada, and the Middle East. As such, the multicenter study more closely mimicked real-life treatment than the MD Anderson trial, which was exclusively conducted at the best cancer center in the United States.

5. Defendants Knew the Targets for Clinical Trials

86. Spectrum met with the FDA prior to its commencement of the MD Anderson trial and the ZENITH20 trial to obtain information about the data expected to achieve BTD status and FDA approval. In the FDA's *Guidance for Industry* on *Clinical Trial Endpoints for the Approval of NonSmall Cell Lung Cancer Drugs and Biologics*, the agency recommends that "applicants meet with the FDA before submitting protocols intended to support NDA or BLA marketing applications." In these pre-emptive meetings and related submissions, the applicant has an opportunity to "to obtain confirmation of the appropriateness of endpoint measures and protocol design for individual trials."

87. CW-2, an executive director overseeing the ZENITH20 trial, explained that Spectrum executives and the FDA determined the target ORR endpoints that Pozi would need to hit ahead of time. CW-2 said that Spectrum knew "the rules of the game, before the trial starts." CW-2 also said that target ORRs are "based on existing therapies," and that Spectrum knew which existing treatment Pozi would be compared to when setting the ORR endpoint.

88. Defendants themselves regularly referenced their meetings with the FDA to discuss expectations. For example, regarding the target for the MD Anderson trial, on May 2, 2017, former CEO Rajesh C. Shrotriya ("Shrotriya") said "[a] Phase II study protocol has been approved by the FDA and has been recently initiated at MD Anderson Cancer Center." And on May 3, 2018, Riga said Spectrum was "in regular discussions with the FDA." On the same call, Turgeon said "we had a preliminary meeting with the agency. This was talking about breakthrough designation. ***We know what the requirements are***."

89. Likewise, Defendants admitted they knew the targets for the ZENITH20 trial. On November 8, 2018, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "We knew exactly . . . what [the FDA] wanted, and I think we gave them the data they

asked for." And on August 9, 2018, while discussing the upcoming ZENITH20 trials for FDA approval, Riga said: "***[O]ur conversations with the agency, obviously, do go into the statistics that are expected, and we're very much aligned with the agency***." Later in the call, he said: "***We've seen very strong early data in an area of high unmet medical need. We have alignment with the agency on our Phase II trial*** . . . ." On February 28, 2019, Lebel similarly admitted: "[W]e've had discussion with the FDA. There's an agreement, ***full understanding of what we need to meet***." On April 28, 2020, Lebel said: "Cohort 1 to 4 were originally designed in collaboration, if you want, with the FDA to support an approval."

90. Throughout the ZENITH20 trial, Defendants admitted that the endpoints for each cohort were "pre-specified" by the FDA. For example, in the Form 10-Q filed with the SEC on August 10, 2020, the Company said: "Cohorts 1-4 are each independently powered for a ***pre-specified*** statistical hypothesis and the primary endpoint is objective response rate ('ORR')." And on November 4, 2020, Lebel unequivocally admitted: "The cohorts were all pre – as ***prespecified endpoints***, they're all independent. The FDA had agreed to that."

91. Spectrum also admitted that it intentionally withheld information about its targets from the public. For example, Turgeon had the following interaction with an investment analyst from Cantor Fitzgerald on October 2, 2019:

> [Analyst:] I wanted to kind of talk about the initial agreement you have with [the FDA] versus what you will have to discuss when you have data. Do you feel confident in the initial agreement being how the second, hopefully, conversation will come? Or do you think there's a possibility that they might need or look for something else and whether [you've got a] provision against that?
>
> [Turgeon:] Yes, first of all, when we got the approval of the single arm trials, started with two cohorts and now we expanded to four, there are amended notes on all the conference intervals. ***We haven't made those public***, as you know, Alethia, because ***we just didn't want to tell the world how high they had to jump***.
>
> And down the road if others in early stage coming out here, so – but we do have [limited confidence] intervals. ***We have all pre-specified endpoints***, all the hypothesis and all the data. ***So, we feel we know how high we have to jump***.

(some alterations in original).

92. Plaintiff has determined the following four crucial ORR values, which Spectrum discussed with the FDA in advance of the trials:

(a) ***Efficacy of Existing Therapies: 22.9% ORR***. As Turgeon disclosed on December 19, 2018, according to "the FDA's guidance on BTD, in the absence of target specific control, the efficacy of poziotinib in patients with mutations had to be compared to non-mutation specific non-small cell lung cancer patients." And that, "[b]ased on published data," the best existing therapy was "combination chemotherapy with VEGF inhibitor with an objective response rate of 22.9%." Later in the call, Riga responded to an analyst question and confirmed it was "consistent with the FDA guidance" to judge Pozi "not versus other TKIs, but maybe against chemo or combinations."

(b) ***Efficacy Required to Show Substantial Improvement (MD Anderson trial): >43% ORR***. In the single-center MD Anderson trial, Pozi demonstrated a 43% ORR, which was not sufficient to achieve BTD status. Accordingly, the BTD target Spectrum discussed with the FDA was higher than 43%.

(c) ***Efficacy Required to Show Clinically Meaningful Advance for Pre-Treated Patients (ZENITH20 – Cohort 1): 30% ORR***. On April 28, 2020, Spectrum disclosed in a press release that "[b]ased on the FDA reviewed protocol, an observed ORR of 30%, with 17% as the lower bound for 95% CI was considered to be the clinically meaningful efficacy in our study."

(d) ***Efficacy Required to Show Clinically Meaningful Advance for Treatment Naïve Patients (ZENITH20 – Cohort 3): >30% ORR***. Although Spectrum never disclosed the target ORR for Cohort 3, it did concede that the target was higher than it was for Cohort 1, because Cohort 3 involved treatment naïve patients. As Lebel admitted on July 27, 2020: "The bar is a little higher, simply because it's first line [treatment]." Spectrum also disclosed in its 2021 Annual Report on SEC Form 10-K the disclosed lower bound was higher than the lower bound for Cohort 1: "Based on the ***pre-specified*** statistical hypothesis for the primary endpoint, the observed lower bound of 18.4% did not meet the ***pre-specified*** lower bound of >20%."

6. Spectrum Ultimately Failed to Hit Its Pre-Specified Endpoints for MD Anderson and ZENITH20 Trials

93. The MD Anderson and ZENITH20 trials demonstrated that Pozi was not safe or effective enough to achieve BTD or FDA approval.

94. On December 19, 2018, Spectrum announced that the FDA had declined to grant BTD status, demonstrating that the 43% ORR obtained in the MD Anderson trial did not meet their pre-specified criteria. For safety data, Spectrum reported on September 24, 2018 that AEs caused 60% of patients in the MD Anderson trial to undergo a dose reduction, while 3% discontinued their treatment altogether.

95. On December 26, 2019, Spectrum announced that Pozi achieved an abysmal 14.8% ORR in Cohort 1, far worse than existing therapies and the 30% ORR FDA target. Months later, on April 28, 2020, Spectrum revealed that significant adverse events had contributed to the poor efficacy outcomes: 88% of patients had dose interruptions and 68% had dose reductions. On February 27, 2020, Spectrum revealed that 10% of patients discontinued due to treatment-related AEs (most commonly diarrhea and rash).

96. On December 22, 2020, Spectrum announced that Cohort 3 had also missed its primary endpoint, returning an ORR of just 27.8%, well below the target of >30%. In this cohort, dose interruption occurred in 94% of patients, and 8% of patients permanently discontinued treatment due to adverse events.

7. Defendants Had Advance Access to and Knew the Disappointing Data for the MD Anderson and ZENITH20 Trials

a. Defendants Had Open Access to Data

97. The MD Anderson and ZENITH20 trials were open-label, which means that Spectrum and its executives, including each Individual Defendant, had access to trial data and results throughout their duration. Indeed, Defendants repeatedly admitted that open-label status meant that they could access the data at will. For example, on May 3, 2018, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q1 2018 results (the "Q1 2018 Earnings Call"). On the call, Riga expressed keen familiarity with the data from the MD Anderson trial,

saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***."

98. For ZENITH20 on May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." On October 2, 2019, Lebel said: "[I]t is an open arm study. ***So, in theory we could look at the data – we could've looked at the data***." And on May 7, 2020, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q1 2020 results (the "Q1 2020 Earnings Call"). On the call, Lebel discussed how ZENITH20 is "an open trial," and that in the upcoming Cohort 5 "there will be regular looking at the data," such that "***[w]e will be able to get some insight, gain insight before we fully enroll***." And on August 10, 2020, when discussing Cohort 4 – the HER2 counterpart to the EGFR Cohort 3 study – Lebel said: "***Obviously, we're looking at data***. It's an open-label study, and we will look at it, so that we're in a good position to discuss with the FDA."

99. On November 7, 2019, an analyst asked Lebel whether Defendants had access to the database of ZENITH20 trial data, and he did not deny it:

> [Analyst:] Just wondering if you can say if the database is locked. And any more granularity on whether it would be earlier or later in December?
>
> [Lebel:] ***So we're not giving you an exact date, neither can I answer whether or not the database is locked***. Remember this is the data – the central imaging lab is in the process of analyzing some of the data and is being sent – when the analysis is complete, it's going to be sent to an independent data review committee who will, in turn, after examining, conducting the analysis, potentially asking a number of questions, then would disclose to us whether or not we've met the primary endpoint.

b. Insiders Confirmed Spectrum Looked at the Data

100. CW-1, a Clinical Research Coordinator at a clinical lab that participated in Spectrum's ZENITH20 trial, represented that Spectrum constantly collected information from participating labs during the trial. The information collected contained detailed data, but also conclusions from the attendant radiologist about whether Pozi worked (*i.e.*, elicited a complete or partial response) for each participant. It took only 3-4 days from the time of the scan for a radiologist to reach these conclusions.

101. CW-1 would regularly upload all of the information in a patient's chart to a database that Spectrum controlled and had full access to. The upload typically took a week to complete after receiving the information. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-1 added that he/she was not aware of any restrictions on who from Spectrum could see the data and was "pretty sure that higher-level people could see it." CW-2 confirmed that Spectrum used and had access to the EDC system that contained data and results collected from the clinical sites, including "efficacy graphs and safety printouts," throughout ZENITH20.

102. CW-1 also provided data and results to Spectrum through other means, including during weekly telephonic meetings with Spectrum personnel to methodically discuss data from the ZENITH20 trial on a patient-by-patient basis. These calls included Dr. Yang, who reported directly to Lebel, and according to CW-1 the calls were "very regimented," in that they "went over every patient on the study" and discussed "the results of each scan, the toxicity and adverse events" for each patient. Before the meetings, Spectrum would send calendar invites with an agenda, and then Spectrum "took meeting minutes" internally.

103. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," and then the rep "reported the information up the chain" at Spectrum. CW-1 added that a weekly newsletter was sent out to "all the sites" participating in the ZENITH20 trial. CW-1 recalls that the newsletter included enrollment numbers and, according to his/her best recollection, information about "AEs and efficacy."

104. One of CW-2's regular tasks was to communicate with the clinical trial sites. Eventually, Lebel made CW-2 the "point person to manage the side effects from Poziotinib," which involved speaking to the doctors and nurses at the clinical trial sites. Once CW-2 entered this role, he/she spent about 50% of his/her time communicating with clinicians. CW-2 reported directly to Lebel and participated in meetings with him in which Spectrum employees discussed updates on the ZENITH20 trial, including the adverse event profile.

105. CW-1 further recounted that Spectrum collected similar information from other clinical sites, and then shared that information with him/her. For example, CW-1 learned through "nonchalant conversations" with Spectrum that "other sites didn't manage the side effects" as well, and that patients who could not tolerate the side effects were dropping out of the ZENITH20 trial.

106. CW-1 said he/she was never made aware that there was an IDRC that reviewed the data, noting that he/she always spoke directly to Spectrum personnel about the data he/she collected. He/she explained that all of the individuals who called him/her to ask about the data from his trial were Spectrum employees.

c. Defendants Referenced Data Before It Was Disclosed

107. Defendants themselves exhibited their access to data from the MD Anderson and ZENITH20 trials by consistently referencing that data. For example, with respect to MD Anderson trial data, on the Company's Q1 2018 Earnings Call on May 3, 2018, Turgeon said: "***I'm feeling pretty good about the early data when you look at that***. How can you not?" On August 9, 2018, Riga said: "***We've seen very strong early data*** in an area of high unmet medical need. We have alignment with the agency on our Phase II trial, and we have a clear shot at BTD." On November 8, 2018, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q3 2018 results (the "Q3 2018 Earnings Call"). On the call, Turgeon specifically referenced AE information straight from the clinic, saying "***the rash was, as I believe, that's 34%, it was manageable. It's what we heard from the site. It's not that different than other TKIs***." Riga added, "***the management of very TKI-like side effects is something that the sites are equipped to do***."

108. And with respect to ZENITH20 data and results, on August 8, 2019 before any ZENITH20 results had been announced, Riga talked about Pozi's data relative to a competing drug, saying: "***We've, obviously, looked at that data in detail***. I think it's pretty early. It looks like that study is starting. ***I think our position, we feel really strong about with the data readout in Q4 and is well ahead in the development life cycle with poziotinib***." And on May 7, 2020, on the Q1 2020 Earnings Call, Lebel discussed how ZENITH20 is a "an open trial," which means "***there will be***

regular looking at the data," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

d. Defendants Withheld This Inside Information for Months

109. Since Defendants had early access to data and results through its EDC database, one can calculate the exact date they had full results based on the date the last patient was enrolled.

110. ***MD Anderson Trial***. On May 3, 2018, Spectrum announced that all EGFR patients in the MD Anderson trial were fully enrolled. On September 24, 2018, Defendants released the full MD Anderson trial data, which revealed that Pozi had an ORR of 43% in the single-center study. But Defendants knew their 43% ORR did not meet the FDA's requirements for BTD status. Investors did not learn this reality until December 19, 2018, when Spectrum announced that the FDA rejected their bid for BTD status. So, from September 24, 2018 to December 19, 2018, Defendants had inside information that the FDA would not grant BTD status to Pozi for treatment of EGFR-mutated patients.

111. ***ZENITH20 – Cohort 1***. ZENITH20 Cohort 1 enrolled its last patient on January 2, 2019. After enrollment, the final confirmatory scan occurs after 8 weeks (56 days) of treatment, then 4 days for the radiologist to make a responsiveness determination, and then 7 days to upload that information to the EDC. Accordingly, Spectrum had fully confirmed results within 67 days after complete enrollment. Thus, Defendants had final results by March 10, 2019. Spectrum did not announce to the public that Cohort 1 had missed its primary endpoint until December 26, 2019. Defendants kept this information to themselves for ***nine months***, from March 10, 2019 to December 26, 2019.

112. ***ZENITH20 – Cohort 3***. The same 67-day calculation applies to Cohort 3. Since the last patient was enrolled on April 28, 2020, Defendants had confirmed results by July 4, 2020. Spectrum did not disclose the data until December 22, 2020, keeping it to themselves for nearly ***six months***.

E. Armed with Inside Knowledge, Defendants Misled Investors About the Efficacy of Pozi and Capitalized

1. Defendants Misrepresented the Efficacy of Existing Therapies

113. Defendants admitted they had a "full understanding" of the BTD requirements from the FDA and knowledge that "the FDA's guidance on BTD" dictated that Pozi would be compared to the best overall therapy for NSCLC, which had a 22.9% ORR. Nevertheless, at the time of Defendants' false and misleading statements regarding the efficacy of existing therapies, they failed to disclose the 22.9% level to investors, and instead repeatedly misrepresented the appropriate comparator to the market. For example, on May 16, 2018, Turgeon claimed Pozi addressed a "huge unmet need" because "current TKIs and other therapies only have a 6% to 8% response rate." And on November 8, 2018, Riga incorrectly insisted that "current available treatments is less than 10%." But Turgeon and Riga failed to disclose that existing TKIs were not the therapy that the FDA would compare with Pozi, and therefore were not the correct comparators for investors to consider.

114. Using these misconceptions, Turgeon led investors to believe that, with respect to Pozi "if I can get a 20% to 30% response rate, I can get a drug approved." In reality, as Turgeon knew at the time based on his conversations with the FDA, Spectrum needed 30% ORR or more to get the drug approved, and greater than 43% ORR to get BTD status.

115. Investors believed Defendants' misrepresentations, and therefore misjudged the efficacy Pozi needed to succeed. On September 6, 2018, an analyst from H.C. Wainwright adopted Turgeon's conclusions, referencing "the range of 20%-30% [ORR] that we would consider necessary for FDA approval."

2. Defendants Misleadingly Expressed Optimism for MD Anderson Trial Results

116. When Defendants announced the 43% ORR MD Anderson trial results on September 24, 2018, they knew it did not measure up to the requirements for BTD previously set by the FDA. Nevertheless, on November 8, 2018, Riga reiterated: "[W]e remain very steadfast in our belief that there is an unmet need, and poziotinib is showing indications of being substantially better than currently available treatments. That's ultimately the criteria."

117. Again, investors bought in and trusted Riga's portrayals of optimism. On November 8, 2018, a Jefferies analyst wrote:

> [That the 43% ORR] is highly clinically meaningful as the current SOC can only achieve <~10-20% ORR with ~2 months PFS. Given the significant unmet medical needs and substantial improvement by pozi in this population, SPPI is confident that pozi meets the criteria for BTD and thus submitted the application for pozi in previously treated EGFR exon20.

118. When Spectrum announced that the FDA rejected the BTD application for Pozi on December 19, 2018, the price of Spectrum common stock fell 38.8% in a single day.

3. Defendants Misleadingly Expressed Optimism for ZENITH20 Cohort 1 and Capitalized

119. After Defendants knew fully confirmed data from Cohort 1 by March 10, 2019, but before they disclosed that data to investors, Defendants made materially false and misleading statements concerning their expectations for Cohort 1. In furtherance of their scheme to boost the stock price and capitalize, Spectrum launched its first ATM financing on April 5, 2019, ***less than one month*** after receiving fully confirmed data and results from Cohort 1.

120. Despite access to and knowledge of results showing Pozi achieved only a 14.8% ORR in Cohort 1, Turgeon and Lebel continued to tout the much higher results from the MD Anderson trial, claiming that the drug would address a "huge medical need" because it "has shown a response rate of 43."

121. Defendants also worked to allay any concerns investment analysts raised. For example, on October 2, 2019, when the Cohort 1 data had been fully compiled and analyzed for months, an analyst from Cantor Fitzgerald specifically questioned the applicability of the MD Anderson trial data to ZENITH20, asking "do you think there's going to be a slippage or a variability as you go for a bigger study with more sites?" In response, Lebel conceded only that single-center studies could produce "a little better" results than multicenter studies. He went on to misleadingly emphasize other aspects of the ZENITH20 trial, such as different dosing schedules and earlier scans, and claimed they "should play in our favor" and would portend a ***better*** result than the MD Anderson trial, even though he had the data showing ZENITH20 already produced a much worse result. Defendants' efforts to mislead investors worked. In Cantor Fitzgerald's next report,

dated November 8, 2019, the analyst parroted Lebel's assurances about the positive effect of dosing and scheduling differences and concluded: "We think that poziotinib is active even considering the single site."

122. Meanwhile, Defendants also downplayed the devastating impact of adverse events on the ZENITH20 trial, never disclosing that 88% of patients had dose interruptions, 68% had dose reductions, and 10% discontinued treatment altogether. On October 2, 2019, Lebel discussed only "very common side effects when you use a TKI," and assured investors that Spectrum's efforts to address those side effects "should play in our favor."

123. Defendants' false assurances amplified investor expectations. On November 10, 2019, a Jefferies analyst echoed Lebel's assurance that earlier scans "could boost ORR some" beyond with 43% ORR demonstrated in the MD Anderson trial, without realizing that ORR had actually already fallen off a cliff.

124. Before this disclosure, on May 16, 2019 and June 6, 2019, with multiple scans and months of data from every participant in Cohort 1 available to him, Turgeon made two outsized sales of stock. Taken together, he sold over 40,000 shares, approximately 9% of his available holdings, for nearly $340,000 in proceeds. Gustafson similarly profited from his access to Cohort 1's disappointing data. Between March 25, 2019 and April 1, 2019, Gustafson sold over 15,000 shares, collectively his second-largest open-market sale ever, for nearly $159,000 in proceeds. Finally, on November 6, 2019, merely weeks before the Company announced the results from Cohort 1, Lebel made his fist sale ever, for 6,963 shares and $56,818 in proceeds.

125. When Defendants announced the failure of Cohort 1 on December 26, 2019, investors suffered tremendous financial losses as the Company's stock price lost over 60% of its value in one busy trading day.

4. Defendants Misleadingly Expressed Optimism for ZENITH20 Cohort 3 and Capitalized

126. Cohort 3 of the ZENITH20 trial was fully enrolled as of April 28, 2020, and fully confirmed results showing Pozi had failed again were available in June 2020. Spectrum initiated several financings after Defendants learned of these results, but before the results were disclosed in

December 2020. In the lead up to each financing, Defendants attempted to boost market sentiment by expressing optimism for the Cohort 3 outcome, even though they knew the ZENITH20 trial had failed.

127. Spectrum initiated its second ATM financing on May 8, 2020. The day before, despite inside knowledge that drug interruption occurred in 94% of patients in Cohort 3, and 8% of patients permanently discontinued treatment due to adverse events, Lebel told investors to expect improved AEs from Cohort 3 relative to Cohort 1. He said, "one would expect that they [Cohort 3 patients] would be more tolerant of adverse events, potentially" and "[w]e understand and we believe on the basis of the data and modeling we've done that we could mitigate the amount of adverse events we see."

128. Spectrum also launched a public offering on July 30, 2020, seeking $65 million from the unknowing public. Three weeks prior, on July 7, 2020, Lebel again attempted to inflate market sentiment about Cohort 3 outcomes, baselessly telling investors that "***cohort 3 could behave differently***" than the failed Cohort 1, knowing Cohort 3 had also failed.

129. Spectrum also initiated its third ATM financing on November 6, 2020. Just ***two days prior***, on November 4, 2020, Turgeon told investors: "I'm really confident in our ability to meet our corporate objectives and advance our programs with the aspiration of bringing new treatments to the patients with cancer who need it."

130. Analysts believed Defendants' assurances. On August 11, 2020, a Jeffries analyst said:

> [W]e looked to cohort 3 (EGFR exon20, similar to cohort 1, but in naive pts vs cohort 1's prior treated) as most likely path for pozi to show positive efficacy, b/c the naive pts are healthier, potentially mitigating tox/AEs presumed to have led to dose reductions/interruptions and poorer efficacy in cohort 1.

And on October 26, 2020, the same analyst reiterated that "cohort 3 is similar to Cohort 1 (previously failed exon20 EGFR), but in healthier pts potentially mitigating tox/AEs presumed to have led to dose reductions/interruptions and poorer efficacy in Cohort 1."

131. Defendants knew or recklessly ignored that Cohort 3 stood no better chance than Cohort 1, and by mid-2020 had access to data confirming that it would also fail. Accordingly, just

before the Cohort 3 results became public, Defendants capitalized on their scheme and unloaded substantial portions of their personal stock holdings. On November 18, 2020, just two weeks after Turgeon told investors he was "really confident in our ability to meet our corporate objectives," Turgeon sold 162,473 shares of Spectrum common stock, 23.5% of his holdings, for proceeds of $671,013. Shortly thereafter, on December 16, 2020, Turgeon sold 150,899 more shares, 28.54% of his remaining holdings, for proceeds of $709,225. In just two trading days, Spectrum's CEO had offloaded more than 45% of his Spectrum holdings, for proceeds of almost $1.4 million. Nearly simultaneously, Gustafson made his own large trade. On December 14, 2020, Gustafson sold 25,696 shares (7.1% of his holdings) for proceeds of $128,480.

132. On December 22, 2020, just days after Turgeon and Gustafson unloaded their shares, Spectrum announced what Defendants had known for months: Cohort 3 failed to meet its primary endpoint with a recorded ORR of 27.8%. This second poor performance acted as a death knell for the market's confidence in Pozi's potential as a treatment for patients with EGFR exon 20 mutations. The following day, December 23, 2020, an analyst from Cantor Fitzgerald wrote "[w]e assign the poziotinib EGFR exon 20 insertion mutation opportunity a 0% POS [probability of success], ***given both cohorts have not met the primary endpoint***."

F. Rolontis Application for FDA Approval

1. Background

133. Rolontis, also an investigational drug, purports to treat a chemotherapy-induced side effect called neutropenia. Neutropenia refers to an abnormally low concentration of white blood cells in a patient's blood, which leaves the patient susceptible to infection. According to Spectrum, Rolontis promotes the production of additional white blood cells in these patients. Other drugs in the marketplace, including market-leader Neulasta, performed the same function as Rolontis. CW-2, who worked at Spectrum during the Class Period, acknowledged that Rolontis was redundant with existing drugs, calling it "trivial" and a "me-too Neulasta."

134. In February and June 2018, Spectrum announced that Rolontis had demonstrated non-inferiority to a comparator drug in its Phase 3 clinical trials. From the outset, Defendants set investors' expectations high about the near-term financial implications of the positive clinical results,

claiming the drug would allow Spectrum to "compete in a multibillion-dollar market with a novel asset." And starting in February 2019, Defendants told investors that they planned to launch Rolontis sometime in 2020.

135. Spectrum manufactured Rolontis at a factory in South Korea, owned and operated by a Korean company, Hanmi Pharmaceuticals. Spectrum lacked control over the Hanmi factory, which fell below FDA standards. CW-2, an executive director at Spectrum who reported directly to Lebel, explained that Hanmi's issues were "common knowledge" inside the company. CW-2 said that, although Spectrum wanted to supervise procedures at the factory, in reality Spectrum did not have control over what happened there. CW-2 recalled that Spectrum executives "sent inspectors to Hanmi to do mock inspections," but Hanmi "failed [the mock inspections] a couple of times." This was because "the quality of plants and people [at Hanmi] were not up to industry standards." Specifically, CW-2 explained that inspections the FDA conducts are focused on documentation, and that Hanmi's "records and documentation was the problem."

2. The Rolontis BLA Was Rejected by the FDA

136. On December 27, 2018, following clinical trials, Spectrum announced its first submission of the Rolontis BLA with the FDA. The FDA did not officially receive the BLA until January 28, 2019, which started the 60-day clock for the FDA to accept or reject the BLA.

137. On March 15, 2019, just two weeks before the FDA was set to announce a determination on the sufficiency of Spectrum's BLA, the Company abruptly withdrew the application. Turgeon later admitted on August 12, 2021, that Spectrum withdrew the BLA in order to avoid an outright rejection from the FDA. Turgeon said: "So, they [the FDA] told us, look[,] in this form, you wouldn't accept it. So you can wait for us to not accept that or you could voluntarily fix this stuff and resubmit. And that's what happened."

138. Defendants assured investors that the problems with the BLA were fixable in the near term, and did not reflect deficiencies with the manufacturing plant itself. Specifically, the Company said in a press release on March 15, 2019 that "Spectrum's decision to withdraw the BLA was the result of the company needing more time to provide certain additional manufacturing-related information." In the same release, Turgeon assured investors that Spectrum was "continuing to have

productive discussions with the FDA and will deliver the additional information needed to support the application[.] . . . We remain confident in the ROLONTIS program and look forward to a successful resubmission and its ultimate approval."

139. Turgeon further explained, on September 11, 2019, that the FDA had "an issue with the CMC portion," which provides the description of the manufacturing plant. But Turgeon minimized the issues, specifically identifying only "formatting issues," "translating things," and "tabling" as issues to address. To fix the CMC "issues," Spectrum set out to change the Hanmi description in the BLA to satisfy the FDA's requirements.

140. Over seven months after the rejection, on October 24, 2019, Spectrum announced that it had resubmitted the Rolontis BLA. The FDA eventually accepted the BLA and Spectrum's amended description of the Hanmi manufacturing plant. The PDUFA date – and the deadline for the FDA to inspect the Rolontis manufacturing facility – was originally October 24, 2020. Because of the coronavirus pandemic, the FDA was unable to travel to South Korea to conduct an inspection of the manufacturing facility, so it deferred the action, giving Spectrum additional time to prepare. On March 16, 2021, Spectrum issued a press release announcing that the FDA had planned the inspection for May 2021.

3. Spectrum Failed the FDA Inspection of the Hanmi Factory

141. The FDA's inspection of the South Korean manufacturing facility ultimately took place from May 25, 2021 through June 2, 2021. At the conclusion of this inspection, the FDA sent Spectrum a CRL that rejected the BLA based on ***ten separate "observations" – or, deficiencies – with the manufacturing process at the Hanmi facility***. A heavily redacted version of the CRL reads as follows:[10]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DBM, Attn: Zhihao Peter Qiu, Ph.D., Director 10903 New Hampshire Avenue; White Oak Building 22 Silver Spring, MD 20993 E-mail: OPFBLAInspection483Responses@fda.hhs.gov	05/25/2021-06/02/2021
	FEI NUMBER 3009350213
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Soojin Kim, Site Director	
FIRM NAME Hanmi Pharm.	STREET ADDRESS 114 Chupalsandan-ro
CITY, STATE, ZIP CODE, COUNTRY Pyeongtaek-si, Gyeonggi-do 17998 Republic of Korea	TYPE ESTABLISHMENT INSPECTED Drug Substance Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The [redacted] manufacturing process is not consistent. Specifically, 12 of [redacted] batches, 6 of [redacted] batches, 4 of [redacted] drug substance [redacted] batches, and 9 of [redacted] and [redacted] batches were rejected for a variety of reasons. Nineteen of the 31 failures were attributed to operator error and equipment failure. See Executive Summary: Trending report for batch rejection rate for a complete description of root cause determinations.

OBSERVATION 2

SOP B:03.4034: Shutdown and Setup Program is inadequate to ensure batch consistency upon resuming manufacturing after scheduled shutdowns. Specifically, in 2019 there were equipment failures that led to [redacted] batch rejections and in 2020, there were equipment failures that resulted in 5 successive [redacted] batch rejections upon resumed manufacturing.

OBSERVATION 3

The [redacted] process performance protocol P-SGC-PPQP-01(1.0) was not followed. Specifically, two batches were excluded from the [redacted] process performance qualification protocol report without sufficient justification. The protocol states that failed batches during PPQ can be excluded when the root cause of a batch failure is extrinsic to the process such as an electrical power

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Richard Ledwidge, Ph.D., Biologist Zhong Zhao, Ph.D., Biologist	06/02/2021

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[10] The CRL was produced in this redacted form, pursuant to Plaintiff's FOIA.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DBM, Attn: Zhihao Peter Qiu, Ph.D., Director 10903 New Hampshire Avenue; White Oak Building 22 Silver Spring, MD 20993 E-mail: OPFBLAInspection483Responses@fda.hhs.gov	05/25/2021-06/02/2021 FEI NUMBER 3009350213

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Soojin Kim, Site Director

FIRM NAME	STREET ADDRESS
Hanmi Pharm.	114 Chupalsandan-ro
CITY, STATE, ZIP CODE, COUNTRY Pyeongtaek-si, Gyeonggi-do 17998 Republic of Korea	TYPE ESTABLISHMENT INSPECTED Drug Substance Manufacturer

outage. Batches [(b) (4)] were excluded from the [(b) (4)] PPQ protocol report even though the root causes of the batch failures were determined to be equipment failure and operator error.

OBSERVATION 4

The Continued Process Verification Protocols P-FGCB-CPVP-01 (2.0), P-LFC-CPVP-01(1.0) and P-SGC-CPVP-01(1.0) to determine the state of process control for all drug substance manufacturing unit operations are inadequate. Specifically, the protocols perform quantitative analysis only on released batches. There are no formalized mechanisms to incorporate batch rejection rates and recurring root causes of batch failures into the analysis to fully assess the degree of process control.

OBSERVATION 5

Process understanding is deficient. Specifically, The [(b) (4)] exhibits pronounced [(b) (4)] changes depending on whether the [(b) (4)] s maintained in [(b) (4)] product-bound, or [(b) (4)] The reasons for the [(b) (4)] changes and the determination of whether potential impurities are eluting into the process stream are not known.

OBSERVATION 6

Documentation for cleaning procedures established for sanitation of product contact equipment are deficient. Specifically, there is no documentation that container lids, that are potentially in contact with process eluates, are cleaned and sanitized before their use in manufacturing. The lids do not have equipment identity numbers and their cleaning is not uniquely documented.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Richard Ledwidge, Ph.D., Biologist Zhong Zhao, Ph.D., Biologist	06/02/2021

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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	FEI NUMBER 3009350213

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Soojin Kim, Site Director

FIRM NAME	STREET ADDRESS
Hanmi Pharm.	114 Chupalsandan-ro
CITY, STATE, ZIP CODE, COUNTRY Pyeongtaek-si, Gyeonggi-do 17998 Republic of Korea	TYPE ESTABLISHMENT INSPECTED Drug Substance Manufacturer

OBSERVATION 7

The material used for the [redacted] assay is not representative of the total [redacted] variation in the [redacted] Specifically, centrifugation of the sample causes it to be non-homogenous such that an aliquot of the upper supernatant used for testing, does not contain all the charge variants that are in the [redacted]

OBSERVATION 8

CAPAs are inadequate. Specifically, the [redacted] was successfully qualified for use in [redacted] manufacturing. The [redacted] unit operation failed due to high pressure. The root cause was determined to be [redacted] packing however, the CAPA did not include any changes to the column performance qualification.

OBSERVATION 9

The protocols (P-SGC-CEX1P-01(1.0), P-SGC-HICP-01(1.0),P-SGC-AEXP-01(1.0), P-SGC-CEX2P-01(1.0), P-FGCB-HICP-01(1.0), P-FGCB-AEXP-01(1.0), and P-FGCB-CEXP-01(1.0)) to assess the [redacted] lifetime studies are inadequate. Specifically, there is no routine microbial testing on end of storage buffer to ensure the [redacted] remain free of potential contamination during storage.

OBSERVATION 10

Conformance to the submitted application is inadequate. The [redacted] of the [redacted] is defined as a critical process parameter with a proposed range of [redacted] in the application. However the current SOP requires a hold time range of [redacted] GMP manufacturing results at the commercial scale have demonstrated that hold times less than [redacted] can result in [redacted]

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		Richard Ledwidge, Ph.D., Biologist Zhong Zhao, Ph.D., Biologist	06/02/2021

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142. The details of the CRL reveal that Defendants had not prepared for the investigation as they had led investors to believe. Indeed, the report identified fundamental deficiencies such as:

- OBSERVATION 1: "[M]anufacturing process is not consistent" due in part to "equipment failure[s]."
- OBSERVATION 2: "Shutdown and Setup Program is inadequate to ensure batch consistency" such that "in 2020, there were equipment failures that resulted in 5 successive [REDACTED] batch rejections upon resumed manufacturing."
- OBSERVATION 4: "There are no formalized mechanisms to incorporate batch rejection rates and recurring root causes of batch failures into the analysis to fully assess the degree of process control."
- OBSERVATION 5: "Process understanding is deficient."
- OBSERVATION 6: "Documentation for cleaning procedures established for sanitation of product contact equipment are deficient. Specifically, there is no documentation that container lids, that are potentially in contact with process eluates, are cleaned and sanitized before their use in manufacturing."
- OBSERVATION 10: "Conformance to the submitted application is inadequate."

143. On August 6, 2021, before the market opened, Spectrum announced receipt of the CRL from the FDA rejecting the Rolontis BLA. Specifically, the press release stated: "The CRL cited deficiencies related to manufacturing and indicated that a reinspection [of the Company's manufacturing facility] will be necessary." In other words, the Company would have to remedy each of the sweeping deficiencies and then restart the lengthy application process. With this news, investors understood that the Company's only remaining prospect for imminent revenue would not materialize, and the Company would instead continue to burn cash for the foreseeable future.

4. Throughout the Process Defendants Claimed They Were in Regular Contact with the FDA and Knew What the Agency Wanted

144. Throughout the BLA process, but before the CRL, Defendants assured investors they had regular contact with the FDA and knew exactly what it required from the Rolontis BLA.

145. In November 2018, leading up to the initial BLA submission, Riga reported that a pre-BLA meeting had taken place and gone well, claiming "[i]n the third quarter, we had a positive pre-BLA meeting with the FDA. Based on that meeting, our team has been diligently working on the BLA submission for ROLONTIS, and we expect to file by the end of the year."

146. After the withdrawal of the initial BLA, but before submission of the second BLA, Defendants insisted they knew exactly what the FDA expected in the CMC portion of the BLA. On May 9, 2019, Turgeon said: "***[W]e're working diligently to prepare the CMC module. I'll remind you, they told us exactly what they want. They're working with us, being very helpful***. So I look forward to the next meeting. ***I'm really pleased with the progress we're making on that part of the trial***." And on August 8, 2019, he again said:

> Listen, ***we are aligned with the FDA***. We had our meeting. We got aligned. We're being thorough. We're being deliberate. And we went with our filing in the fourth quarter as we said. This was – the questions that we had to answer were in module 3, which is in the CMC section only. And again, we're being like I said, thorough and deliberate and plan on filing this in the fourth quarter.

147. And on the same call, Lebel insisted that the Company was fully aligned with the FDA, stating: "[W]e recently had a productive meeting with the FDA to further discuss their expectation around module 3, which is the module focused on manufacturing."

148. During the pendency of the second BLA, Defendants continued to stress their alignment with the FDA and their readiness for the inspection. On October 2, 2019, Turgeon said:

> [W]e did have a positive meeting with the agency where they walked us through. We wanted to make sure we knew exactly what they wanted in the CMC section. . . . ***I think we are going to have everything they want and then some***. And we're checking and rechecking to make sure, a lot of experts looking at us.

149. On November 7, 2019, Lebel said: "[W]e've had productive dialogue with the FDA. We implemented their guidance, provided additional data and rewrote and reorganized certain sections of the file resulting in a strong submission." And Riga said: "We worked closely with the agency. We implemented their guidance. We feel that we've learned from their feedback and put together a strong package and look forward to that action date."

G. Defendants Misled Investors About Their Readiness for the FDA Inspection and Capitalized

1. Spectrum Claimed They Voluntarily Withdrew the BLA

150. On March 15, 2019, when Spectrum received the directive from the FDA to withdraw the first BLA or suffer a rejection, the Company was less than a month away from launching its first ATM financing on April 5, 2019. Accordingly, the Company could not afford bad news that would

impact the stock price and impair its ability to raise money. Thus, Defendants decided to mislead throughout the course of the ATM financing, which closed on March 20, 2020.

151. Rather than admit that the FDA rejected the BLA, Defendants claimed ***Spectrum*** decided to withdraw it on its own accord. In the press release announcing the withdrawal on March 15, 2019, Defendants said, "the company has ***voluntarily withdrawn*** its Biologics License Application," and assured investors that the withdrawal was "Spectrum's decision." On September 11, 2019, during the 2019 Morgan Stanley Conference, Turgeon claimed "we made the decision" to withdraw, and falsely and misleadingly described the interaction with the FDA:

> So about 2 weeks before the end of March, we had a meeting with the agency, and they said "By the way, we have an issue with the CMC portion. We had 2 weeks left until the 60 days were up." And I said, "We need some additional information, ***nothing that was over the top***, but we need this information." And we have formatting issues. We had a lot of translation because a lot of it was done in Korea, and they didn't like the way we were translating things. We had to reformat some of the tabling and things.
>
> So the bottom line is, we had to get some additional information. We knew we couldn't do it by the 29th of March. ***So we said***, "***Why don't we voluntarily – we'll pull it." Then they said, "Fine," without prejudice***. They said, "We'll give you exactly what we want." ***We've since met with them. They gave it to us, and I'm happy to tell you we're in good shape to launching – to submit it in the fourth quarter***.

152. On November 7, 2019, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q3 2019 results ("Q3 2019 Earnings Call"). On the call, Turgeon again said: "***[W]e voluntarily withdrew our BLA application earlier this year***."

153. Analysts accepted Defendants' assurances. For example, on the day Spectrum announced it was withdrawing the BLA, an analyst at Guggenheim wrote: "[W]e believe most of the information requested is administrative" and that the withdrawal would simply "shift out our launch assumption to 2021 from 2020," which was a "silver lining" because it would allow the Company to focus on the "pivotal poziotinib readouts in [the second half of 2019] and 2020." On October 2, 2019, the same analyst reported that "SPPI noted" that the information the FDA requested was "minor and straightforward."

154. Turgeon took advantage of the inflated stock price for personal gain, by making a large and uncharacteristic sale of stock. In a series of two transactions on May 16, 2019 and June 6, 2019, Turgeon unloaded 9% of his shares for total proceeds of $340,000.

2. Spectrum Resubmitted the BLA and Defendants Falsely and Misleadingly Said They Were Prepared for the FDA Inspection

155. Near the end of 2020, Spectrum was desperate for cash with only $46 million cash runway on hand as reported in the Company's Form 10-Q with the SEC for Q4 2020. Spectrum schemed to raise money by inflating Spectrum's stock price and launching a third ATM offering. In the weeks leading up to this launch, Spectrum assured the market that, despite its limited resources, the Company was investing heavily in its preparation for the FDA's inspection of the Hanmi manufacturing facility. Spectrum failed to tell the market, however, that it actually lacked control over the deficient Hanmi plant and had ***failed*** the mock inspections they touted.

156. For example, in an October 26, 2020 press release, Turgeon said: "'***The manufacturing facility is ready for inspection*** and we are eager to assist the FDA in completing their assessment as soon as possible.'" And on a November 4, 2020 conference call, he said: "***We are absolutely ready for this inspection. We've been ready for a long time. We welcome it***." During the same call, Lebel and Turgeon stressed all the extra effort they had put in to ensure the manufacturing facility was FDA-compliant, including "mock inspections," "Spectrum boots on [the] ground" in Korea to examine the facility, and the utilization of "outside experts" who "not only run these mock inspections, but . . . know exactly what people – what the FDA is looking for [in] an inspection." And on May 13, 2021, Turgeon again told investors "***[w]e're prepared for the inspection***, we're looking forward to it."

157. Analysts again believed Defendants' misrepresentations. On October 26, 2020, a JMP Securities analyst said "we are confident that the company will take all reasonable and appropriate actions to facilitate the inspection required for a near-term regulatory decision." And on March 31, 2021, a Cantor Fitzgerald Analyst said: "We think FDA approval of Rolontis is becoming more de-risked as the FDA has confirmed a time frame with Spectrum for review of its

manufacturing facility. We find it comforting that the FDA has already met with Hanmi personnel and has gone through the procedures for the South Korea inspection."

158. During this time period, Turgeon decided to personally divest himself from the Company while he simultaneously filled outside investors with hope for the future. Just 14 days after launching the third ATM financing to extract more money from investors, and just 12 days after telling investors he was "really confident" in the future of the Company, Turgeon initiated two more inside sales on November 18, 2020 and December 16, 2020 in which he sold 45% of his shares for $1.4 million.

159. On March 16, 2021, Spectrum announced that the FDA scheduled the pre-approval inspection of the Hanmi manufacturing facility at the end of May 2021. Despite Defendants' previous assurances regarding the FDA's inspection, the news prompted a large sell-off of Defendants' personal shares. On March 15, 2021 and March 16, 2021, all four Individual Defendants sold unusually large amounts of their Spectrum common stock. Turgeon sold over 68,000 shares (his second-largest open-market sale ever) for nearly $250,000 in proceeds; Gustafson sold over 36,000 shares (his largest open-market sale ever) for over $134,000 in proceeds; Riga sold over 42,000 shares (his second-largest sale ever) for over $154,000 in proceeds; and Lebel sold over 41,000 shares (his largest sale ever, 18.6% of his holdings) for over $150,000 in proceeds. Lebel's sale was his largest ever up to that point.

H. Fallout

1. Spectrum Abandoned Pozi as Treatment of EGFR-Mutated Patients

160. Ultimately, Pozi failed to demonstrate sufficient efficacy to warrant FDA approval for treatment of EGFR-mutated patients, and Spectrum's competitors stepped in to take its prospective place in the market. The FDA approved Rybrevant as the first targeted treatment for patients with NSCLC with EGFR Exon 20 insertion mutations on May 21, 2021. The FDA granted accelerated approval of mobocertinib for the same group of patients on September 16, 2021.

161. Shortly after the Class Period, Riga acknowledged that Spectrum's EGFR journey had ended. On March 17, 2022, Spectrum hosted an earnings call with investors and analysts to

discuss the Company's Q4 2021 results. On that call, Riga announced that the Company would no longer pursue its EGFR application for Pozi. In his opening remarks, Riga told analysts and investors:

> To date, our studies in EGFR exon 20 insertion mutations have not met their primary endpoints despite demonstrating strong clinical activity.
>
> In addition, there are now 2 drugs approved in this space. As a result, we will no longer be pursuing poziotinib as a stand-alone therapy for EGFR patients.

2. Turgeon and Gustafson Abruptly Departed from the Company

162. At the end of 2021, less than a year after Turgeon and Gustafson used material non-public information to sell off their stock, Turgeon abruptly left the Company, followed shortly thereafter by Gustafson. On December 1, 2021, less than four years into his tenure as CEO, Spectrum suddenly announced that Turgeon "retired." On February 23, 2022, Spectrum announced that Gustafson would follow Turgeon out the door. The Company did not provide any benign explanation for these departures, releasing opaque statements that said "we would like to thank [Turgeon] for his many contributions to the company," and that Gustafson had "provided notice of his resignation to pursue other professional opportunities."

3. ZENITH20 Cohort 2 Failed and a Securities Case Followed

163. In late November 2022, the FDA issued a CRL to Spectrum denying approval of Pozi for patients with the HER2 exon 20 insertion mutation (Cohort 2 patients). A couple weeks later, a group of investors filed a class action complaint against Spectrum, Riga, and Lebel, among others, in the Southern District of New York alleging the defendants violated §§10(b) and 20(a) of the Exchange Act for materially misrepresenting the safety and efficacy data from the ZENITH20 trial. *See Christiansen v. Spectrum Pharms., Inc.*, No. 22-CV-10292 (VEC) (S.D.N.Y.). On January 23, 2024, Judge Caproni denied the defendants' motion to dismiss based in part on Spectrum's statement that the Company and the FDA were "aligned" with respect to the dosage regimen used in the ZENITH20 trial. There, the court found the plaintiff adequately alleged the alignment statement was materially false and misleading because "FDA officials had allegedly told Defendants that Spectrum did not have adequate data for the agency to approve Spectrum's dosing regimen for the [ZENITH20

Cohort 2] Study." *Christiansen v. Spectrum Pharms., Inc.*, 2024 WL 246020, at *7 (S.D.N.Y. Jan. 23, 2024). In fact, according to the CRL Spectrum received in November 2022, the FDA had repeatedly expressed concern to Spectrum regarding Pozi's adverse event profile in the years leading up to the CRL.

4. Assertio Acquired Spectrum and Spectrum Common Stock Was Delisted

164. On April 25, 2023, only five months after Spectrum received the FDA's CRL regarding Cohort 2 patients, Assertio announced it entered into a definitive agreement pursuant to which it would acquire all outstanding shares of Spectrum. Assertio's announcement did not mention anything about Pozi or the ZENITH20 trial, placing it firmly in Spectrum's rearview mirror. The merger closed on July 27, 2023, when Assertio announced that its stockholders and the stockholders of Spectrum approved the agreement. A few days later, after July 31, 2023, the NASDAQ delisted Spectrum's stock. The last closing stock price for Spectrum on the NASDAQ was $1.03, down drastically from its Class Period high of $24.82 per share.

VI. MATERIALLY FALSE AND MISLEADING STATEMENTS

A. Statements Concerning Pozi

1. Statements During the MD Anderson Trial

165. Throughout the MD Anderson trial, Defendants misrepresented Pozi's prospects for success by: (i) failing to disclose what the FDA considered the best available treatment for NSCLC patients, and instead encouraging investors to compare Pozi to less effective treatments that the FDA did not consider relevant; (ii) misrepresenting the target efficacy for FDA approval; and (iii) expressing optimism for BTD status when they knew or recklessly disregarded that Pozi failed to meet the requisite standard. For a timeline of relevant events and statements, *see* Appendix A attached hereto. For additional indicia of scienter beyond that listed below, *see* §VII, *infra*.

a. Efficacy of Existing Treatments

Turgeon

166. On March 6, 2018, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q4 2017 results (the "Q4 2017 Earnings Call"). On the call, his first as CEO, Turgeon made the following materially false and misleading statement:

> First, let me start with poziotinib. In the fourth quarter of 2017, preliminary data from a Phase II study at MD Anderson Cancer Center was presented at the World Conference on Lung Cancer in Japan. Promising data was presented with an unconfirmed partial response rate of 73% in the first 11 patients. These data are encouraging for patients who have very few options, if any. As a reminder, poziotinib is being developed for patients who have non-small cell lung cancer with exon 20 insertion mutations in EGFR or HER2. These mutations cause steric hindrance in the binding pocket for tyrosine kinase inhibitors, which result in ***limited activity in these mutations from existing TKIs***. The prognosis for these patients is poor with median progressive – progression-free survival of about 2 months. ***Current therapies are unsatisfactory, and there is significant unmet need in this population***. It is hypothesized that poziotinib, due to its relatively small molecular size and flexibility, can circumvent steric hindrance related to exon 20 insertion mutations.

167. On the Company's Q1 2018 Earnings Call held on May 3, 2018, Turgeon made the following materially false and misleading statement:

> Patients, as you know, with this disease have a PFS of 1.8 months. So it's a terrible, terrible prognosis. ***Current therapies only have less than 10% – I think a 6% to 10% response rate***. So we have ***huge unmet need***, terrible prognosis.

168. At a May 16, 2018, Bank of America Merrill Lynch Healthcare Conference, Turgeon made the following materially false and misleading statements:

> I don't know if you know this, lung cancer is a leading cause of death of all the cancers because, not because of the prevalence but because the percent of the people who actually die. So it's ***very, very high unmet need, very important***. When you get to these exon 20 insertion mutations, talking about unmet need, you have a progression-free survival of only 1.8 months and ***current TKIs and other therapies only have a 6% to 8% response rate, huge unmet need***.

169. Turgeon's statements in ¶¶166-168 were materially false and misleading or omitted material information because he misrepresented the level of ORR necessary for Pozi to exceed existing therapies. Turgeon's assertions that "current therapies only have less than 10%" ORR and that "current TKIs and other therapies only have a 6% to 8% response rate," directed investors'

attention to the incorrect comparison. In reality, Spectrum and the FDA had already agreed on a protocol that compared Pozi to the best existing therapy for NSCLC, which had 22.9% ORR, and therefore the FDA would not consider anything under 30% ORR as clinically meaningful and worthy of approval. Turgeon later admitted on December 19, 2018, that according to "the FDA's guidance on BTD, in the absence of target specific control, the efficacy of poziotinib in patients with mutations had to be compared to non-mutation specific non-small cell lung cancer patients." And, "[b]ased on published data," the best existing therapy was "combination chemotherapy with VEGF inhibitor with an objective response rate of 22.9%." On April 28, 2020, Spectrum disclosed in a press release what Defendants knew when Turgeon made the statements, that "[b]ased on the FDA reviewed protocol, an observed ORR of 30% . . . was considered to be the clinically meaningful efficacy in our study."

170. Turgeon's statements in ¶¶166-168 were knowingly or recklessly false and misleading or omitted material information because from the outset of the MD Anderson trial in March 2017, it was clear Pozi would be compared to existing therapies with much higher efficacies, including because:

(a) Executives admitted they developed a protocol with the FDA that set the appropriate comparator and the efficacy needed for BTD status. On May 2, 2017, former CEO Shrotriya admitted that "[a] Phase II study protocol has been approved by the FDA" for the MD Anderson trial. And on May 3, 2018, Riga admitted Spectrum was "in regular discussions with the FDA." On the same call, Turgeon likewise admitted: "***We know what the requirements are***." On November 8, 2018, on the Company's Q3 2018 Earnings Call, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "***We knew exactly . . . what [the FDA] wanted***, and I think we gave them the data they asked for."

(b) Insiders have confirmed that Spectrum knew the FDA's expectations heading into the ZENITH20 trial. CW-2 explained that Spectrum knew "the rules of the game, before the trial starts," and that target ORRs are "based on existing therapies," and that Spectrum knew which existing treatment Pozi would be compared to when setting the ORR endpoint.

(c) Defendants must have known about the appropriate comparator, as it would be absurd for them not to understand the most effective treatment for the patient population they targeted.

Riga

171. On August 9, 2018, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q2 2018 results. On the call, Riga made the following materially false and misleading statement:

> [Guggenheim Analyst:] Okay. Last one, then I will get back in line, promise. Presumably, you did agree to a kind of – some kind of response rate in PFS hurdle. Can you say what is? Is that in line with your prior thinking?
>
> [Riga:] Yes. It's a great question. I think you start with memory lane of where we are and ***current available treatments is less than 10%***. So obviously this is a patient population that needs a solution because today's solutions simply aren't working.

172. On the Company's Q3 2018 Earnings Call on November 8, 2018, Riga made the following materially false and misleading statement:

> Let me provide some highlights from the data that Dr. Heymach presented at the conference. ***In the EGFR cohort, there was a 43% confirmed objective response rate in the evaluable population. This compares favorably to an overall response rate of less than 10% with available TKIs and a rate of less than 20% with the current standard of care second-line agents***.

173. Riga's statements in ¶¶171-172 were materially false and misleading or omitted material information because he misrepresented the level of ORR necessary for Pozi to exceed existing therapies and achieve FDA approval. Riga's assertions that "current available treatments is less than 10%" ORR and that Pozi "compares favorably to an overall response rate of less than 10% with available TKIs and a rate of less than 20% with the current standard of care second-line agents," directed investors' attention to the incorrect comparisons. In reality, Spectrum and the FDA had already agreed on a protocol that compared Pozi to the best existing therapy for NSCLC, which had a 22.9% ORR. Turgeon later admitted on December 19, 2018, that according to "the FDA's guidance on BTD, in the absence of target specific control, the efficacy of poziotinib in patients with mutations had to be compared to non-mutation specific non-small cell lung cancer patients." And

that, "[b]ased on published data," the best existing therapy was "combination chemotherapy with VEGF inhibitor with an objective response rate of 22.9%." Accordingly, the FDA would not consider anything under 30% ORR as clinically meaningful and worthy of approval. On April 28, 2020, Spectrum disclosed in a press release that "[b]ased on the FDA reviewed protocol, an observed ORR of 30% . . . was considered to be the clinically meaningful efficacy in our study."

174. Riga's statements in ¶¶171-172 were knowingly or recklessly false and misleading or omitted material information because from the outset of the MD Anderson trial in March 2017, it was clear Pozi would be compared to existing therapies with much higher efficacies, including because:

(a) Executives admitted they developed a protocol with the FDA that set the appropriate comparator and the efficacy needed for BTD status. On May 2, 2017, former CEO Shrotriya admitted that "[a] Phase II study protocol has been approved by the FDA" for the MD Anderson trial. And on May 3, 2018, Riga admitted Spectrum was "in regular discussions with the FDA." On the same call, Turgeon likewise admitted: "***We know what the requirements are***." On August 9, 2018, while discussing the upcoming ZENITH20 trials for FDA approval, Riga said: "***[O]ur conversations with the agency, obviously, do go into the statistics that are expected, and we're very much aligned with the agency***." Later in the call, he said: "***We've seen very strong early data in an area of high unmet medical need. We have alignment with the agency on our Phase II trial*** . . . ." Later, on April 28, 2020, Spectrum acknowledged the FDA required an observed ORR of 30%.

(b) Insiders have confirmed that Spectrum knew the FDA's expectations heading into the ZENITH20 trial. CW-2 explained that Spectrum knew "the rules of the game, before the trial starts," and that target ORRs are "based on existing therapies," and that Spectrum knew which existing treatment Pozi would be compared to when setting the ORR endpoint.

(c) Defendants must have known about the appropriate comparator, as it would be absurd for them not to understand the most effective treatment for patient population they targeted.

b. Target for FDA Approval

Turgeon

175. At a May 16, 2018 Bank of America Merrill Lynch Healthcare Conference, Turgeon made the following materially false and misleading statement:

> Now let me give you a perspective. Before we started this trial, right here in Las Vegas, I had 16 of the world thought leaders in lung, in a room in a hotel down the street. And I said, okay, tell me, what is a home run here, in your guys' eyes? You guys do this for a living. ***I know as a drug developer, if I can get a 20% to 30% response rate, I can get a drug approved***. But what's the home run that I really want to look forward and hope for? Here's what they told me 2 things, they said, if you get a 40% or more response rate, that's a home run.

176. Turgeon's statement in ¶175 was materially false and misleading or omitted material information because he misrepresented the level of ORR necessary for Pozi to achieve FDA approval. Turgeon inaccurately claimed that "I know as a drug developer, if I can get a 20% to 30% response rate, I can get a drug approved." In reality, Spectrum and the FDA had already agreed on a protocol that required 30% ORR – and nothing less – in order to secure approval. Lebel later disclosed, in November 2020, that "the FDA had agreed" to "prespecified endpoints" as part of its conversations with Spectrum.

177. Turgeon's statement in ¶175 was knowingly or recklessly false and misleading or omitted material information because from the outset of the ZENITH20 trial in October 2017, Turgeon knew or recklessly disregarded the bar for FDA approval was clear, including because:

(a) Turgeon and other executives admitted that prior to these statements they developed a protocol with the FDA that set the appropriate level for FDA approval. On August 9, 2018, while discussing the upcoming ZENITH20 trials for FDA approval, Riga said: "[O]ur conversations with the agency, obviously, do go into the statistics that are expected, and we're very much aligned with the agency." Later in the call, he said: "***We've seen very strong early data in an area of high unmet medical need. We have alignment with the agency on our Phase II trial*** . . . ." On November 8, 2018, on the Company's Q3 2018 Earnings Call, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "We knew ***exactly . . . what [the FDA]***

wanted, and I think we gave them the data they asked for." And on October 2, 2019, Turgeon admitted that the endpoints for ZENITH20 were "pre-specified."

(b) Insiders have confirmed that Spectrum knew the FDA's expectations heading into the ZENITH20 trial. CW-2, who worked on the ZENITH20 trial, explained that Spectrum executives and the FDA determined the target ORR endpoints that Pozi would need to hit in each cohort to support FDA approval. According to CW-2, Defendants knew "the rules of the game, before the trial starts."

(c) Defendants must have known about the appropriate level for FDA approval, as Pozi was their most promising drug and the key to the Company's future.

c. Baseless Optimism

Riga

178. On November 8, 2018, during the Company's Q3 2018 Earnings Call, Riga made the following materially false and misleading statement:

> Sure, sure. David, we're thrilled to have submitted the application for BTD, and we remain very steadfast in our belief that there is an unmet need, and ***poziotinib is showing indications of being substantially better than currently available treatments. That's ultimately the criteria***. Now the FDA will decide ultimately and where that goes, but there are multiple regulatory pathways besides BTD, like you had mentioned in the fast track setting and others that exist, but we are thrilled to have applied for that application and ***believe that the drug qualifies***.

179. Riga's statement in ¶178 was materially false and misleading or omitted material information because he incorrectly suggested that Pozi could still achieve BTD status. Riga's assertions that "poziotinib is showing indications of being substantially better than currently available treatments," led investors to believe that Pozi satisfied the "substantial improvement" criteria for BTD. In reality, Spectrum and the FDA had already agreed on a protocol that required ***over*** 43% ORR in order to secure BTD status.

180. Riga's statement in ¶178 was knowingly or recklessly false and misleading or omitted material information because by September 24, 2018, it was clear that the FDA would not grant BTD to Pozi, including because:

(a) From the outset of the clinical trial in March 2017, he knew that BTD would require an ORR of ***over*** 43%, including because:

(i) Executives admitted they developed a protocol with the FDA that set the appropriate comparator and the efficacy needed for BTD status. On May 2, 2017, former CEO Shrotriya admitted that "[a] Phase II study protocol has been approved by the FDA" for the MD Anderson trial. And on May 3, 2018, Riga admitted Spectrum was "in regular discussions with the FDA." On the same call, Turgeon likewise admitted: "***We know what the requirements are***." And on August 9, 2018, while discussing the upcoming ZENITH20 trials for FDA approval, Riga said: ***"[O]ur conversations with the agency, obviously, do go into the statistics that are expected, and we're very much aligned with the agency***." Later in the call, he said: "***We've seen very strong early data in an area of high unmet medical need. We have alignment with the agency on our Phase II trial*** . . . ." Later, on April 28, 2020, Spectrum acknowledged the FDA required an observed ORR of 30%.

(ii) Insiders have confirmed that Spectrum knew the FDA's expectations heading into the ZENITH20 trial. CW-2 explained that Spectrum knew "the rules of the game, before the trial starts," and that target ORRs are "based on existing therapies," and that Spectrum knew which existing treatment Pozi would be compared to when setting the ORR endpoint.

(iii) Defendants must have known about the appropriate comparator, as it would be absurd for them not to understand the most effective treatment for the patient population they targeted.

(b) By September 24, 2018, Riga knew that Pozi did not meet the pre-specified criteria for BTD status.

(i) The MD Anderson trial began in March 2017 and was open-label, meaning that Riga could access trial data and results as they came in. Spectrum announced that enrollment was complete on May 3, 2018.

(ii) On September 24, 2018, Spectrum announced that Pozi demonstrated an ORR of 43% in the MD Anderson trial, demonstrating that the Company had fully confirmed

results as of that date. Although investors now knew the results, they did not know – and Riga did – that the results did not meet the pre-specified criteria for BTD provided by the FDA.

2. Statements During ZENITH20 – Cohort 1

181. Throughout Cohort 1 of the ZENITH20 trial, Defendants misrepresented Pozi's prospects for success by: (i) expressing optimism for Pozi, when they knew or recklessly disregarded that Pozi failed to meet its primary endpoint for efficacy; (ii) referring to outdated results from the MD Anderson trial without disclosing the worse and more robust results from Cohort 1; and (iii) failing to disclose the devastating impact AEs had on Cohort 1 patients and efficacy results. For a timeline of Cohort 1 events and statements, *see* Appendix B attached hereto. For additional indicia of scienter beyond that listed below, *see* §VII, *infra*.

a. Baseless Optimism

Turgeon

182. At a October 2, 2019 Cantor Fitzgerald Global Healthcare Conference, Turgeon made the following materially false and misleading statement in response to an analyst question about competition for Pozi:

> [Analyst:] Obviously there is [Rain], there is Takeda, probably others in the future. I guess how do you think about let's say particularly with Takeda, like your profile with Poziotinib versus their drug, 788?
>
> [Turgeon:] Listen, we keep an eye on that, obviously. The first thing I will say, ***it's nice to be in a pole position and we certainly are that because we have two fully enrolled trials and – where others are just getting started***. And the pivotal would TAK-788, which you saw, is it looks like it's not started yet, but they are about to start. So, that puts us in a pretty good lead.

183. Turgeon's statement in ¶182 was materially false and misleading or omitted material information because he incorrectly suggested that Pozi was progressing ahead of its competition. Turgeon's assertions that Pozi was "in a pole position" with "a pretty good lead" over other drugs, failed to disclose that:

(a) Pozi had just failed to demonstrate efficacy in Cohort 1. In reality, seven months prior to these statements, in March 2019, Spectrum had fully confirmed data showing that

Pozi demonstrated only 14.8% ORR, well short of the 30% ORR efficacy endpoint required for FDA approval.

(b) The material difference in results at a small single-center study at MD Anderson, a world-renowned cancer center with world-renowned oncologists, and results in a generalized and more representative multicenter study at a variety of centers across the world. In addition, as CW-2 explained, single-center studies allow for "unconscious biases" or incentives to "minimize, delay or not report AEs" in order to keep patients on the drug for a longer period of time. Defendants failed to disclose that Pozi would perform materially worse in the upcoming multicenter trial.

184. Turgeon's statement in ¶182 was knowingly or recklessly false and misleading or omitted material information because by March 10, 2019, it was clear Cohort 1 would not produce positive results for the Company, including because:

(a) From the outset of the ZENITH20 trial in October 2017, Turgeon knew the primary endpoint for Cohort 1 was 30% ORR, including because:

(i) A former executive director at Spectrum who worked on the ZENITH20 trial explained that Spectrum executives and the FDA determined the target ORR endpoints that Pozi would need to hit in each cohort to support FDA approval. CW-2 said that Spectrum knew "the rules of the game, before the trial starts." Defendants repeatedly admitted that they knew the targets. On August 9, 2018, while discussing the upcoming ZENITH20 trials for FDA approval, Riga said: "[O]ur conversations with the agency, obviously, do go into the statistics that are expected, and we're very much aligned with the agency." Later in the call, he said: "***We've seen very strong early data in an area of high unmet medical need. We have alignment with the agency on our Phase II trial*** . . . ." On November 8, 2018, on the Company's Q3 2018 Earnings Call, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "***We knew exactly . . . what [the FDA] wanted***, and I think we gave them the data they asked for." And on September 11, 2019, Turgeon admitted: "***When we design the trials, went to the agency and got the approval on the ends***, the powering, et cetera."

(ii) Throughout the ZENITH20 trial, Defendants admitted that the endpoints for each cohort were "pre-specified" by the FDA. For example, on October 2, 2019, Turgeon admitted: "We have all ***pre-specified*** endpoints, all the hypothesis and all the data. So, we feel we know how high we have to jump." And in the Company's Form 10-Q filed with the SEC on August 10, 2020 and signed by Turgeon, the Company said "Cohorts 1-4 are each independently powered for a ***pre-specified*** statistical hypothesis and the primary endpoint is objective response rate ('ORR')."

(iii) The Company revealed the Cohort 1 pre-specified endpoint on April 28, 2020, when it stated that "[b]ased on the FDA reviewed protocol, an observed ORR of 30% . . . was considered to be the clinically meaningful efficacy in our study." While this endpoint was not revealed to the public until April 2020, through their statements concerning meetings with the FDA and designing the trials with the FDA, Defendants confirm that they understood an ORR of 30% to be the primary endpoint by August 2018.

(b) By March 10, 2019, Turgeon also knew or recklessly disregarded that fully confirmed Cohort 1 data did not meet the 30% ORR threshold, including because:

(i) the ZENITH20 trial was open-label, which means Turgeon had access to the data throughout the trial.

(ii) Defendants conceded that the open nature of the ZENITH20 trial granted them access to the information as it came in. For example, on October 2, 2019, Lebel said: "[I]t is an open arm study. So, in theory we could look at the data – we could've looked at the data." And on May 7, 2020, on the Company's Q1 2020 Earnings Call, Lebel discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "there will be regular looking at the data," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(iii) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors:

"I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(iv) Insiders confirmed that Spectrum had the data. CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics shared real-time data, including efficacy data and results, on Spectrum's EDC system. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2, a former executive director at Spectrum who worked on Cohort 1 of the ZENITH20 trial, corroborated CW-1's account that Spectrum personnel had access to the EDC system, including "efficacy graphs and safety printouts," during the ZENITH20 trial. CW-1 also had weekly meetings with Spectrum personnel, including Lebel's direct report, to discuss data, and Spectrum took minutes of these meetings. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," which the rep then "reported the information up the chain" at Spectrum.

Lebel

185. At the October 2, 2019, Cantor Fitzgerald Global Healthcare Conference, Lebel made the following materially false and misleading statements:

> [Analyst:] And I guess as you think about, obviously your first study was in one site, M.D. Anderson. I mean do you – I know Takeda had multiple sites, but do you think there's going to be a slippage or a variability as you go for a bigger study with more sites?
>
> [Lebel:] Yes, so that's a good point. Whenever you have a single site study in general the data often is a little better than when you do a multi-centric study. ***But we made some slight change to the study that should help us*** (technical difficulty) could go against us. But so the original data done at M.D. Anderson, single site. The images, the scans were read locally and when they were would run into toxicity, the way in which they would reduce the amount of drug the patient received were by an increment of 4 mg.
>
> So, currently dose on both studies, you start at 16 mg. And if you run into some toxicity Dr. Heymach would have dropped it by 4 and by 4. We've made some change where we don't drop the doses fast; so we drop the dose by 2 mg. ***So, that***

> ***should allow us to keep patient on drug longer and that's the name of the game***. The longer the patient is on drug that is when you could derive the benefit.
>
> The other thing that we have done, we have central imaging labs and we also introduced a first read – Dr. Heymach in the first study was reading the – looking for a response every eight weeks. We've introduced a first scan at four weeks. So, that should allow us to pick up response at an earlier time and potentially add time on duration of response. ***It should play in our favor***.
>
> The other thing we've done as well is, other than a lower increment of when you drop the dose. Also additionally what we've done is we prophylax every patient for – against diarrhea. One of the very common side effects when you use a TKI, it's a problem with the class, and actually is an indication that the drug blocks the EGFR receptor. They get rash and they get diarrhea or it impacts the gut. So we are prophylaxing all the patients against diarrhea. Dr. Heymach was not doing that, so ***that should play in our favor***.

186. Lebel's statements in ¶185 were materially false and misleading or omitted material information because he incorrectly suggested that Pozi could perform better in Cohort 1 than it previously performed in the MD Anderson trial. Lebel's assertions that certain modifications to the ZENITH20 trial "should play in our favor" failed to disclose to unknowing investors that:

(a) Pozi had just failed to demonstrate efficacy in Cohort 1. In reality, seven months prior to these statements, in March 2019, Spectrum had fully confirmed data showing that Pozi achieved a 14.8% ORR, which was well short of the 30% ORR efficacy endpoint required for FDA approval.

(b) the material difference in results at a small single-center study at MD Anderson, a world-renowned cancer center with world-renowned oncologists, and results in a generalized and more representative multicenter study at a variety of centers across the world. In addition, as CW-2 explained, single-center studies allow for "unconscious biases" or incentives to "minimize, delay or not report AEs" in order to keep patients on the drug for a longer period of time. Defendants failed to disclose that Pozi would perform materially worse in the upcoming multicenter trial.

187. Lebel's statements in ¶185 were knowingly or recklessly false and misleading or omitted material information because by March 10, 2019, it was clear Cohort 1 would not produce positive results for the Company, including because:

(a) From the outset of the ZENITH20 trial in October 2017, Lebel knew the primary endpoint for Cohort 1 was 30% ORR, including because:

(i) A former executive director at Spectrum who worked on the ZENITH20 trial explained that Spectrum executives and the FDA determined the target ORR endpoints that Pozi would need to hit in each cohort to support FDA approval. CW-2 said that Spectrum knew "the rules of the game, before the trial starts."

(ii) Defendants repeatedly admitted that they knew the targets. On August 9, 2018, while discussing the upcoming ZENITH20 trials for FDA approval, Riga said: "[O]ur conversations with the agency, obviously, do go into the statistics that are expected, and we're very much aligned with the agency." Later in the call, he said: "***We've seen very strong early data in an area of high unmet medical need. We have alignment with the agency on our Phase II trial*** . . . ." On November 8, 2018, on the Company's Q3 2018 Earnings Call, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "***We knew exactly . . . what [the FDA] wanted***, and I think we gave them the data they asked for." And on September 11, 2019, Turgeon admitted: "***When we design the trials, went to the agency and got the approval on the ends***, the powering, et cetera."

(iii) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(iv) Throughout the ZENITH20 trial, Defendants admitted that the endpoints for each cohort were "pre-specified" by the FDA. For example, on October 2, 2019, Turgeon admitted: "We have all ***pre-specified*** endpoints, all the hypothesis and all the data. So, we feel we know how high we have to jump." And on November 4, 2020, Lebel unequivocally admitted: "***The cohorts were all pre – as prespecified endpoints***, they're all independent. The FDA had agreed to that."

(v) The Company revealed the Cohort 1 pre-specified endpoint on April 28, 2020, when it stated that "[b]ased on the FDA reviewed protocol, an observed ORR of 30 . . . was considered to be the clinically meaningful efficacy in our study."

(b) By March 10, 2019, Lebel also knew or recklessly disregarded that fully confirmed Cohort 1 data did not meet the 30% ORR threshold, including because the ZENITH20 trial was open-label, which means Lebel had access to the data throughout the trial.

(i) Lebel conceded that the open nature of the ZENITH20 trial granted them access to the information as it came in. For example, on October 2, 2019, he said: "[I]t is an open arm study. So, in theory ***we could look at the data*** – we could've looked at the data." And on May 7, 2020, on the Company's Q1 2020 Earnings Call, he discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "***there will be regular looking at the data***," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(ii) Insiders confirmed that Spectrum had the data. CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics shared real-time data, including efficacy data and results, on Spectrum's EDC system. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2, a former executive director at Spectrum who worked on Cohort 1 of the ZENITH20 trial, corroborated CW-1's account that Spectrum personnel had access to the EDC system, including "efficacy graphs and safety printouts," during the ZENITH20 trial. CW-1 also had weekly meetings with Spectrum personnel, including Lebel's direct report, to discuss data, and Spectrum took minutes of these meetings. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," which the rep then "reported the information up the chain" at Spectrum.

Riga

188. On August 8, 2019, Spectrum held an earnings call to discuss Q2 2019 financial results (the "Q2 2019 Earnings Call"). On the call, Riga made the following materially false and misleading statement:

> [Analyst:] Okay. Great. And now a question post the TAK-788 data at ASCO, I just want to get your thoughts on what that data versus the pozi data. If both of them hold up, what this could mean for the market? So maybe this is for Tom. And also, what the market is going to look like? And then, any thoughts on the discontinuations of 788 due to adverse events, which was higher than poziotinib.
>
> [Riga:] Hey, Ed, it's Tom. We've, obviously, looked at that data in detail. I think it's pretty early. It looks like that study is starting. I think our position, ***we feel really strong about with the data readout in Q4 and is well ahead in the development life cycle with poziotinib***. So we'll have to see what that market looks like. I think what it really says is that there is real unmet need for this patient population. As more and more compounds come into the full, I think it speaks to the solutions that patients need, and we're pleased to be at the forefront of that.

189. Riga's statement in ¶188 was materially false and misleading or omitted material information because he incorrectly suggested that Cohort 1 could yield positive results. Riga's assertion that he felt "really strong about . . . the data readout" failed to disclose that:

(a) Pozi had just failed to demonstrate efficacy in Cohort 1. In reality, five months prior to these statements, in March 2019, Spectrum had fully confirmed data showing that Pozi demonstrated only a 14.8% ORR, well short of the 30% ORR efficacy endpoint required for FDA approval.

(b) The material difference in results at a small single-center study at MD Anderson, a world-renowned cancer center with world-renowned oncologists, and results in a generalized and more representative multicenter study at a variety of centers across the world. In addition, as CW-2 explained, single-center studies allow for "unconscious biases" or incentives to "minimize, delay or not report AEs" in order to keep patients on the drug for a longer period of time. Defendants failed to disclose that Pozi would perform materially worse in Cohort 1.

190. Riga's statement in ¶188 was knowingly or recklessly false and misleading or omitted material information because by March 10, 2019, it was clear Cohort 1 would not produce positive results for the Company, including because:

(a) From the outset of the ZENITH20 trial in October 2017, Riga knew the primary endpoint for Cohort 1 was 30% ORR, including because:

(i) A former executive director at Spectrum who worked on the ZENITH20 trial explained that Spectrum executives and the FDA determined the target ORR endpoints that Pozi would need to hit in each cohort to support FDA approval. CW-2 said that Spectrum knew "the rules of the game, before the trial starts."

(ii) Defendants repeatedly admitted that they knew the targets. On August 9, 2018, while discussing the upcoming ZENITH20 trials for FDA approval, Riga said "our conversations with the agency, obviously, do go into the statistics that are expected, and we're very much aligned with the agency." Later in the call, he said: "***We've seen very strong early data in an area of high unmet medical need. We have alignment with the agency on our Phase II trial*** . . . ." On November 8, 2018, on the Company's Q3 2018 Earnings Call, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "We ***knew exactly . . . what [the FDA] wanted***, and I think we gave them the data they asked for." And on September 11, 2019, Turgeon admitted: "***When we design the trials, went to the agency and got the approval on the ends***, the powering, et cetera."

(iii) Throughout the ZENITH20 trial, Defendants admitted that the endpoints for each cohort were "pre-specified" by the FDA. For example, on October 2, 2019, Turgeon admitted: "We have all ***pre-specified*** endpoints, all the hypothesis and all the data. So, we feel we know how high we have to jump." And in the 10-Q filed with the SEC on August 10, 2020 and signed by Turgeon, the Company said "Cohorts 1-4 are each independently powered for a ***pre-specified*** statistical hypothesis and the primary endpoint is objective response rate ('ORR')." And on November 4, 2020, Lebel unequivocally admitted: "***The cohorts were all pre – as prespecified endpoints***, they're all independent. The FDA had agreed to that."

(iv) The Company revealed the Cohort 1 pre-specified endpoint on April 28, 2020, when it stated that "[b]ased on the FDA reviewed protocol, an observed ORR of 30% . . . was considered to be the clinically meaningful efficacy in our study."

(b) By March 10, 2019, Riga also knew or recklessly disregarded that fully confirmed Cohort 1 data did not meet the 30% ORR threshold, including because the ZENITH20 trial was open-label, which means Riga had access to the data throughout the trial.

(i) Defendants conceded that the open nature of the ZENITH20 trial granted Defendants access to the information as it came in. For example, on October 2, 2019, Lebel said: "[I]t is an open arm study. So, in theory we could look at the data – we could've looked at the data." And on May 7, 2020, on the Company's Q1 2020 Earnings Call, he discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "there will be regular looking at the data," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(ii) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(iii) Insiders confirmed that Spectrum had the data. CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics shared real-time data, including efficacy data and results, on Spectrum's EDC system. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2, a former executive director at Spectrum who worked on Cohort 1 of the ZENITH20 trial, corroborated CW-1's account that Spectrum personnel had access to the EDC system, including "efficacy graphs and safety printouts," during the ZENITH20 trial. CW-1 also had weekly meetings with Spectrum personnel, including Lebel's direct report, to discuss data, and Spectrum took minutes of these meetings. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," which the rep then "reported the information up the chain" at Spectrum.

b. Outdated Results

Turgeon

191. At the September 11, 2019, Morgan Stanley Healthcare, Turgeon made the following materially false and misleading statement:

> We – MD Anderson did a Phase II, specifically in exon 20, both EGFR and HER2. ***And last year, at World Lung, showed a 43% overall response rate, which was much higher than anything***. There's nothing that works. There's nothing indicated for these poor patients. The prognosis is very poor. PFS is 1.8 months. They progress very quickly and die. And so this is what the – where the exciting data came from.

192. Turgeon's statement in ¶191 was materially false and misleading or omitted material information because he emphasized old results without disclosing more recent and reliable – but less impressive – Cohort 1 results. Turgeon's reference to outdated results failed to disclose:

(a) That Pozi had just failed to demonstrate efficacy in Cohort 1. In reality, six months prior to these statements, in March 2019, Spectrum had fully confirmed data showing that Pozi demonstrated only 14.8% ORR, well short of the 43% ORR Turgeon highlighted.

(b) The material difference in results at a small single-center study at MD Anderson, a world-renowned cancer center with world-renowned oncologists, and results in a generalized and more representative multicenter study at a variety of centers across the world. In addition, as CW-2 explained, single-center studies allow for "unconscious biases" or incentives to "minimize, delay or not report AEs" in order to keep patients on the drug for a longer period of time. Defendants failed to disclose that Pozi would perform materially worse in Cohort 1.

193. Turgeon's statement in ¶191 was knowingly or recklessly false and misleading or omitted material information because by March 10, 2019, it was clear that Pozi had performed far worse in Cohort 1 than the MD Anderson trial data, demonstrating an efficacy of just 14.8% ORR, including because the ZENITH20 trial was open-label, which means Turgeon had access to the data throughout the trial.

(a) Defendants conceded that the open nature of the ZENITH20 trial granted them access to the information as it came in. For example, on October 2, 2019, Lebel said: "[I]t is an open arm study. So, in theory we could look at the data – we could've looked at the data." And on May

7, 2020, on the Company's Q1 2020 Earnings Call, Lebel discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "there will be regular looking at the data," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(b) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(c) Insiders confirmed that Spectrum had the data. CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics shared real-time data, including efficacy data and results, on Spectrum's EDC system. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2, a former executive director at Spectrum who worked on Cohort 1 of the ZENITH20 trial, corroborated CW-1's account that Spectrum personnel had access to the EDC system, including "efficacy graphs and safety printouts," during the ZENITH20 trial. CW-1 also had weekly meetings with Spectrum personnel, including Lebel's direct report, to discuss data, and Spectrum took minutes of these meetings. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," which the rep then "reported the information up the chain" at Spectrum.

Lebel

194. At the October 2, 2019, Cantor Fitzgerald Global Healthcare Conference, Lebel made the following materially false and misleading statement:

> And ***we are in a leading position [right] now*** in developing a tyrosine kinase inhibitor that has [a] unique ability to work against Exon 20 in vitro in collaboration with M.D. Anderson. As shown Dr. Heymach there, who is the Chief of Thoracic Oncology, showed in a substantial – in the largest series in the world of Exon 20

> patients, ***has shown a response rate of 43% or so*** and a tolerable side effect profile in line with other tyrosine kinase inhibitors.

195. Lebel's statement in ¶194 was materially false and misleading or omitted material information because he emphasized old results without disclosing more recent and reliable – but less impressive – Cohort 1 results. Lebel's reference to outdated results failed to disclose:

(a) That Pozi had just failed to demonstrate efficacy in Cohort 1. In reality, seven months prior to these statements, in March 2019, Spectrum had fully confirmed data showing that Pozi demonstrated only 14.8% ORR, well short of the 43% ORR Lebel highlighted.

(b) The material difference in results at a small single-center study at MD Anderson, a world-renowned cancer center with world-renowned oncologists, and results in a generalized and more representative multicenter study at a variety of centers across the world. In addition, as CW-2 explained, single-center studies allow for "unconscious biases" or incentives to "minimize, delay or not report AEs" in order to keep patients on the drug for a longer period of time. Defendants failed to disclose that Pozi would perform materially worse in Cohort 1.

196. Lebel's statement in ¶194 was knowingly or recklessly false and misleading or omitted material information because by March 10, 2019, it was clear that Pozi had performed far worse in Cohort 1 than the MD Anderson trial data, demonstrating an efficacy of just 14.8% ORR, including because:

(a) The ZENITH20 trial was open-label, which means Lebel had access to the data throughout the trial.

(b) Lebel conceded that the open nature of the ZENITH20 trial granted them access to the information as it came in. For example, on October 2, 2019, he said: "[I]t is an open arm study. So, in theory ***we could look at the data*** – we could've looked at the data." And on May 7, 2020, on the Company's Q1 2020 Earnings Call, he discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "***there will be regular looking at the data***," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(c) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD

Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(d) Insiders confirmed that Spectrum had the data. CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics shared real-time data, including efficacy data and results, on Spectrum's EDC system. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2, a former executive director at Spectrum who worked on Cohort 1 of the ZENITH20 trial and reported directly to Lebel, corroborated CW-1's account that Spectrum personnel had access to the EDC system, including "efficacy graphs and safety printouts," during the ZENITH20 trial. CW-1 also had weekly meetings with Spectrum personnel, including Lebel's direct report, to discuss data, and Spectrum took minutes of these meetings. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," which the rep then "reported the information up the chain" at Spectrum.

The Company

197. Spectrum's Form 10-Q filings filed with the SEC on May 9, 2019, August 9, 2019, and November 7, 2019 each contained signed certifications from Turgeon and Gustafson attesting, among other things, that:

> Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

In each of these filings, Spectrum made the following, or substantially similar, materially false and misleading statements:

> In September 2018, we announced preliminary poziotinib data from the University of Texas, MD Anderson Cancer Center ("MD Anderson") Phase 2 NSCLC study which were released during an oral presentation at the IASLC 19th

> World Conference on Lung Cancer. The MD Anderson study is the single largest data set of patients with an exon 20 mutation in EGFR or HER2. This Phase 2 study demonstrated high anti-tumor activity for poziotinib in metastatic, heavily pretreated EGFR exon 20 mutant NSCLC, a group for which no targeted agents have proved to be effective to date. This data is summarized below:
>
> - ***In 44 evaluable patients with EGFR exon-20 mutations, the confirmed overall response rate was 43% and disease control rate was 90%***. Median progression free survival was 5.5 months.
> - In evaluable patients with HER2 exon-20 mutations, the confirmed overall response rate was 42% and disease control rate was 83%. Median progression free survival was 5.1 months.
> - ***EGFR-related toxicities (including rash, diarrhea, and paronychia) were manageable and required dose reductions in 60% of patients***. Discontinuation due to poor tolerance was rare (approximately 3% of patients).

198. Spectrum's Form S-3 Registration statement for the ATM offerings, filed with the SEC on April 5, 2019, contained the following materially false and misleading statement:

> In collaboration with The University of Texas MD Anderson Cancer Center ("MD Anderson"), an investigator-sponsored Phase 2 trial was initiated in NSCLC patients with EGFR or HER2 exon-20 mutations. ***This Phase 2 Study demonstrated high anti-tumor activity for poziotinib in metastatic, heavily pretreated EGFR exon 20 mutant NSCLC, a group for which no targeted agents have proven to be effective to date***. In addition to the MD Anderson study, we have an ongoing pivotal Phase 2 global study with active sites in the U.S., Canada, and Europe. On January 2, 2019 we announced full enrollment of the cohort 1 (N=87) for previously treated NSCLC patients with EGFR exon 20 insertion mutations with sites across the U.S., Europe, and Canada.

199. The Company's statements in ¶¶197-198 were materially false and misleading or omitted material information because it emphasized old results without disclosing more recent and reliable – but less impressive – Cohort 1 results. The reference to outdated results failed to disclose:

(a) that Pozi had just failed to demonstrate efficacy in Cohort 1. In reality, prior to these statements, in March 2019, Spectrum had fully confirmed data showing that Pozi demonstrated only 14.8% ORR, well short of the 43% ORR the Company highlighted. Pozi had also performed far worse in terms of safety in Cohort 1, with 88% of patients requiring dose interruptions, 68% dose reductions, and 10% discontinued treatment.

(b) the material difference in results at a small single-center study at MD Anderson, a world-renowned cancer center with world-renowned oncologists, and results in a generalized and more representative multicenter study at a variety of centers across the world. In addition, as CW-2 explained, single-center studies allow for "unconscious biases" or incentives to "minimize, delay or not report AEs" in order to keep patients on the drug for a longer period of time. Defendants failed to disclose that Pozi would perform materially worse in Cohort 1.

200. The Company's statements in ¶¶197-198 were knowingly or recklessly false and misleading or omitted material information because by March 10, 2019, it was clear that Pozi had performed far worse in Cohort 1 than the MD Anderson trial data, demonstrating an efficacy of just 14.8% ORR, including because:

(a) the ZENITH20 trial was open-label, which means Defendants had access to the data throughout the trial.

(b) Defendants conceded that the open nature of the ZENITH20 trial granted them access to the information as it came in. For example, on October 2, 2019, Lebel said: "[I]t is an open arm study. So, in theory ***we could look at the data*** – we could've looked at the data." And on May 7, 2020, on the Company's Q1 2020 Earnings Call, Lebel discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "***there will be regular looking at the data***," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(c) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(d) Insiders confirmed that Spectrum had the data. CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics shared real-time data, including efficacy data and results, on Spectrum's EDC system. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with

"inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2, a former executive director at Spectrum who worked on Cohort 1 of the ZENITH20 trial, corroborated CW-1's account that Spectrum personnel had access to the EDC system, including "efficacy graphs and safety printouts," during the ZENITH20 trial. CW-1 also had weekly meetings with Spectrum personnel, including Lebel's direct report, to discuss data, and Spectrum took minutes of these meetings. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," which the rep then "reported the information up the chain" at Spectrum.

c. Adverse Events

Lebel

201. At the October 2, 2019, Cantor Fitzgerald Global Healthcare Conference, Lebel made the following materially false and misleading statement:

> The other thing we've done as well is, other than a lower increment of when you drop the dose. ***Also additionally what we've done is we prophylax every patient for – against diarrhea***. One of the very common side effects when you use a TKI, it's a problem with the class, and actually is an indication that the drug blocks the EGFR receptor. They get rash and they get diarrhea or it impacts the gut. So we are prophylaxing all the patients against diarrhea. ***Dr. Heymach was not doing that, so that should play in our favor***.

202. On March 10, 2020, at the Barclays Global Healthcare Conference, Lebel made the following materially false and misleading statements:

> The confirmed objective response rate, as I mentioned to you, was 14.8%. That was below what we wanted. However, the patients who responded showed the duration of response that was 7.4 months. So that's a very good response rate. Meaning if you're one of the lucky patients to respond, your response last a significant amount of time clinically. So that's very important. The median progression-free survival was 4.2 months. ***And the safety profile was in line with other second-generation EGFR tyrosine kinase inhibitor***.
>
> So while we missed the primary endpoint, if you go to Slide 7, you will see there a waterfall plot that shows what I believe is unequivocal activity. The great majority of patients had tumor-size reduction. ***And the other thing we've mentioned previously is that 2/3 of the patients had some form of dose interruption, could be as short as 1 day or as long as 2 weeks. And 2/3 had dose reduction. So we have 2/3 with interrupted therapy and 2/3 who had some form of dose reductions***. We

> will be presenting this data in much greater detail at the 11th Annual Congress on Pulmonary and Respiratory Medicine in Amsterdam next week, March 18, and that will be followed by a call in all – from management.

203. Lebel's statements in ¶¶201-202 were materially false and misleading or omitted material information because he incorrectly suggested that Spectrum could attain a manageable level of adverse events in Cohort 1. Lebel's assertions that Spectrum's effort to "prophylax" against diarrhea "should play in our favor" failed to disclose to unknowing investors that:

(a) prior to these statements, in March 2019, Spectrum had fully confirmed safety data showing AEs so dramatic that patients could not stay on the drug. As Spectrum later reported, in Cohort 1 ***88%*** (not 2/3) of patients had dose interruptions, ***68%*** had dose reductions, and ***10%*** of patients discontinued treatment altogether. This was far worse than existing TKI Tagrisso, which had dose reductions in just 2.9% of patients. CW-1, a researcher at a clinic for Cohort 1 for ZENITH20, recalled that "toxicity levels were tough" in the trial and the biggest issue for patients taking Pozi. CW-1 tried to mitigate AEs with steroids and antibiotics, using "magic mouthwash" and even "butt paste," but side effects remained a major problem. CW-2, an executive director at Spectrum, confirmed that AEs were a major issue during the ZENITH20 trials, because the "16-milligram-per-day dose was far higher than what was needed, and it corresponded with bad side effects." CW-2 remembers that "85 percent of patients had serious side effects" such as rashes and diarrhea, and the AEs "were disabling, intolerable." According to CW-2, many patients who wanted to continue with the drug had to stop because the AEs were so severe.

(b) the AEs impacted Spectrum's efficacy results in the ZENITH20 trial, in which Pozi demonstrated efficacy of just 14.8% ORR, well short of the 30% ORR efficacy endpoint required for FDA approval. CW-1 said it was his/her understanding that Pozi failed because of "toxicity and the AEs. If the AEs had been managed better by the sites, they would have had better outcomes." CW-2 confirmed that AEs "affected the efficacy of the drug if patients dropped out."

(c) the material difference in results at a small single-center study at MD Anderson, a world-renowned cancer center with world-renowned oncologists, and results in a generalized and more representative multicenter study at a variety of centers across the world. In

addition, as CW-2 explained, single-center studies allow for "unconscious biases" or incentives to "minimize, delay or not report AEs" in order to keep patients on the drug for a longer period of time. Defendants failed to disclose that Pozi would perform materially worse in Cohort 1.

204. Lebel's statements in ¶¶201-202 were knowingly or recklessly false and misleading or omitted material information because by March 10, 2019, it was clear that Cohort 1 demonstrated high rates of adverse events, including because:

(a) the ZENITH20 trial was open-label, which means Lebel had access to safety data throughout the trial.

(b) Defendants conceded that the open nature of the ZENITH20 trial granted them access to the information as it came in. For example, on October 2, 2019, Lebel said: "[I]t is an open arm study. So, in theory ***we could look at the data*** – we could've looked at the data." And on May 7, 2020, on the Company's Q1 2020 Earnings Call, he discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "***there will be regular looking at the data***," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(c) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(d) CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics regularly shared data, including adverse events data and results, with Spectrum via the EDC database. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2 – Lebel's direct report - confirmed that Spectrum used the EDC system during the trial, and that it contained data and results collected from the clinical sites, including "efficacy graphs and safety printouts." CW-1 also said

that, during the Cohort 1 trial, he/she attended weekly meetings with Spectrum personnel including Lebel's direct report, where attendees discussed safety data and Spectrum took meeting minutes. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," and the rep then "reported the information up the chain" at Spectrum.

3. Statements During ZENITH20 – Cohort 3

205. Throughout Cohort 3 of the ZENITH20 trial, Defendants misrepresented Pozi's prospects for success by: (i) expressing optimism for Pozi, when they knew or recklessly disregarded that Pozi failed to meet its primary endpoint for efficacy; (ii) referring to outdated results from the MD Anderson trial without disclosing worse and more robust results from Cohort 3; and (iii) failing to disclose the devastating impact AEs had on Cohort 3 patients and efficacy results. For a timeline of Cohort 3 events and statements, *see* Appendix C attached hereto. For additional indicia of scienter beyond that listed below, *see* §VII, *infra*.

a. Baseless Optimism

Turgeon

206. On November 4, 2020, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q3 2020 results (the "Q3 2020 Earnings Call"). On the call, Turgeon made the following materially false and misleading statement:

> ***I'm really confident in our ability to meet our corporate objectives and advance our programs with the aspiration of bringing new treatments to the patients with cancer who need it***.

207. Turgeon's statement in ¶206 was materially false and misleading or omitted material information because he incorrectly suggested that the Company still held out hope for Pozi's Cohort 3 results. Turgeon's assertions that he was "really confident" that Spectrum could "bring[] new treatments to the patients with cancer who need it," failed to disclose that Pozi had just failed to demonstrate efficacy in Cohort 3 of its ZENITH20 clinical trial. In reality, four months prior to these statements, on July 4, 2020, Spectrum had fully confirmed data showing that Pozi achieved a 27.8% ORR, which fell short of the >30% ORR efficacy endpoint required for FDA approval in that patient population.

208. Turgeon's statement in ¶206 was knowingly or recklessly false and misleading or omitted material information because by July 4, 2020, it was clear that Cohort 3 results would not achieve FDA approval, including because:

(a) By May 9, 2019, when Spectrum began enrollment in Cohort 3, Turgeon knew or recklessly disregarded that the primary endpoint for Cohort 3 was >30% ORR, including because:

(i) A former executive director at Spectrum who worked on the ZENITH20 trial explained that Spectrum executives and the FDA determined the target ORR endpoints that Pozi would need to hit in each cohort to support FDA approval. CW-2 said that Spectrum knew "the rules of the game, before the trial starts."

(ii) Defendants repeatedly admitted that they knew the targets. On August 9, 2018, while discussing the upcoming ZENITH20 trials for FDA approval, Riga said: "[O]ur conversations with the agency, obviously, do go into the statistics that are expected, and we're very much aligned with the agency." Later in the call, he said: "***We've seen very strong early data in an area of high unmet medical need. We have alignment with the agency on our Phase II trial*** . . . ." On November 8, 2018, on the Company's Q3 2018 Earnings Call, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "We ***knew exactly . . . what [the FDA] wanted***, and I think we gave them the data they asked for." On November 8, 2018, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "We knew exactly . . . what [the FDA] wanted, and I think we gave them the data they asked for."

(iii) Throughout the ZENITH20 trial, Defendants admitted that the endpoints for each cohort were "pre-specified" by the FDA. For example, on October 2, 2019, Turgeon admitted: "We have all ***pre-specified*** endpoints, all the hypothesis and all the data. So, we feel we know how high we have to jump." And in the 10-Q filed with the SEC on August 10, 2020 and signed by Turgeon, the Company said "Cohorts 1-4 are each independently powered for a ***pre-specified*** statistical hypothesis and the primary endpoint is objective response rate ('ORR')."

(iv) Although Spectrum never disclosed the target ORR for Cohort 3, it did concede that the target was higher than the 30% ORR for Cohort 1, because Cohort 3 involved

treatment naïve patients. As Lebel admitted on July 27, 2020: "The bar is a little higher, simply because it's first line [treatment]."

(b) By July 4, 2020, Turgeon also knew or recklessly disregarded that fully confirmed Cohort 3 data did not meet the >30% ORR threshold, including because:

(i) The ZENITH20 trial was open-label, which means Turgeon had access to the data throughout the trial.

(ii) Defendants conceded that the open nature of the ZENITH20 trial granted them access to the information as it came in. For example, on October 2, 2019, Lebel said: "[I]t is an open arm study. So, in theory ***we could look at the data*** – we could've looked at the data." And on May 7, 2020, on the Company's Q1 2020 Earnings Call, Lebel discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "***there will be regular looking at the data***," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(iii) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(iv) Insiders confirmed that Spectrum had the data. CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics shared real-time data, including efficacy data and results, on Spectrum's EDC system. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2, a former executive director at Spectrum who worked on the ZENITH20 trial, corroborated CW-1's account that Spectrum personnel had access to the EDC system, including "efficacy graphs and safety printouts," during the ZENITH20 trial. CW-1 also had weekly meetings with Spectrum personnel, including Lebel's direct report, to discuss data, and Spectrum took minutes of these

meetings. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," which the rep then "reported the information up the chain" at Spectrum. CW-2 explained: "It was the understanding when I left [in Q3 2020]" within Spectrum that Pozi would not be approved by the FDA due to the intolerable side effects and their impact on efficacy.

(v) On November 18, 2020, Turgeon sold 162,473 shares of Spectrum common stock for a $671,013 in proceeds. Those shares represented 23.5% of Turgeon's holdings at the time. Two days later, on December 16, 2020, Turgeon sold 150,899 more shares, 28.54% of his remaining holdings, for proceeds of $709,225. In total, Spectrum's CEO had offloaded almost half of his Spectrum holdings, for proceeds of almost $1.4 million.

Lebel

209. On July 7, 2020, Spectrum hosted a special call with investors and analysts, during which Lebel made the following materially false and misleading statement in response to an analyst question:

> [Analyst:] Okay. And then just thinking about cohort 3, anything that – from a cohort 1 versus cohort 3 standpoint, beyond obviously the patient population being first line, any other considerations you think about would be helpful, if you want to – if you can highlight that.
>
> [Lebel:] Sure. Well, we used to be asked that question after cohort 1, is cohort – does cohort 2 or 3 have any chance? And now you – we kept saying, well, they're independent cohorts, and they might behave differently. And certainly, it looks like they have right now. ***So cohort 3 could behave differently***. The bar is a little higher, simply because it's first line. And as you know, in the literature, the bar is a little higher, but it's very hard to predict. I think we're going to have to wait. ***It's only going to be a few months until we are able to provide you that piece of information***.

210. Lebel's statement in ¶209 was materially false and misleading or omitted material information because he incorrectly suggested that the Company still held out hope for Pozi's Cohort 3 results. Lebel's assertion that "cohort 3 could behave differently," failed to disclose that Pozi had just failed to demonstrate efficacy in Cohort 3 of its ZENITH20 clinical trial. In reality, prior to these statements, in June 2020, Spectrum had fully confirmed data showing that Pozi achieved a

27.8% ORR, which fell short of the >30% ORR efficacy endpoint required for FDA approval in that patient population.

211. Lebel's statement in ¶209 was knowingly or recklessly false and misleading or omitted material information because by July 4, 2020, it was clear that Cohort 3 results would not achieve FDA approval, including because:

(a) By May 9, 2019, when Spectrum began enrollment in Cohort 3, Lebel knew or recklessly disregarded that the primary endpoint for Cohort 3 was >30% ORR, including because:

(i) A former executive director at Spectrum who worked on the ZENITH20 trial explained that Spectrum executives and the FDA determined the target ORR endpoints that Pozi would need to hit in each cohort to support FDA approval. CW-2 said that Spectrum knew "the rules of the game, before the trial starts."

(ii) Defendants repeatedly admitted that they knew the targets. On August 9, 2018, while discussing the upcoming ZENITH20 trials for FDA approval, Riga said: "[O]ur conversations with the agency, obviously, ***do go into the statistics that are expected***, and we're very much aligned with the agency." Later in the call, he said: "***We've seen very strong early data in an area of high unmet medical need. We have alignment with the agency on our Phase II trial*** . . . ." On November 8, 2018, on the Company's Q3 2018 Earnings Call, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "We ***knew exactly . . . what [the FDA] wanted***, and I think we gave them the data they asked for." On November 8, 2018, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "***We knew exactly . . . what [the FDA] wanted***, and I think we gave them the data they asked for."

(iii) Throughout the ZENITH20 trial, Defendants admitted that the endpoints for each cohort were "pre-specified" by the FDA. For example, on October 2, 2019, Turgeon admitted: "We have all ***pre-specified*** endpoints, all the hypothesis and all the data. So, we feel we know how high we have to jump." And on September 11, 2019, Turgeon admitted: "***When we design the trials, went to the agency and got the approval on the ends***, the powering, et cetera." And in the 10-Q filed with the SEC on August 10, 2020 and signed by Turgeon, the Company said

"Cohorts 1-4 are each independently powered for a ***pre-specified*** statistical hypothesis and the primary endpoint is objective response rate ('ORR')."

(iv) Although Spectrum never disclosed the target ORR for Cohort 3, it did concede that the target was higher than the 30% ORR for Cohort 1, because Cohort 3 involved treatment naïve patients. As Lebel admitted on July 27, 2020: "The bar is a little higher, simply because it's first line [treatment]."

(b) By July 4, 2020, Lebel also knew or recklessly disregarded that fully confirmed Cohort 3 data did not meet the >30% ORR threshold, including because the ZENITH20 trial was open-label, which means Lebel had access to the data throughout the trial.

(i) Defendants conceded that the open nature of the ZENITH20 trial granted them access to the information as it came in. For example, on October 2, 2019, Lebel said: "[I]t is an open arm study. So, in theory ***we could look at the data*** – we could've looked at the data." And on May 7, 2020, on the Company's Q1 2020 Earnings Call, Lebel discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "***there will be regular looking at the data***," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(ii) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(iii) Insiders confirmed that Spectrum had the data. CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics shared real-time data, including efficacy data and results, on Spectrum's EDC system. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2, a former executive director at Spectrum who worked on the ZENITH20 trial, corroborated CW-

1's account that Spectrum personnel had access to the EDC system, including "efficacy graphs and safety printouts," during the ZENITH20 trial. CW-1 also had weekly meetings with Spectrum personnel, including Lebel's direct report, to discuss data, and Spectrum took minutes of these meetings. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," which the rep then "reported the information up the chain" at Spectrum. CW-2 explained: "It was the understanding when I left [in Q3 2020]" within Spectrum that Pozi would not be approved by the FDA due to the intolerable side effects and their impact on efficacy.

b. Outdated Results

The Company

212. Spectrum's prospectus supplement for a public offering, dated July 30, 2020, contained the following false and misleading statements from the Company:

> In collaboration with The University of Texas MD Anderson Cancer Center, an investigator-sponsored Phase 2 trial was initiated in NSCLC patients with EGFR or HER2 exon 20 mutations (the "MD Anderson Phase 2 Trial") in March 2017. In September 2018, we announced preliminary poziotinib data from the MD Anderson Phase 2 Trial, which were released during an oral presentation at the IASLC 19th World Conference on Lung Cancer. This Phase 2 trial demonstrated anti-tumor activity for poziotinib in metastatic, heavily pretreated EGFR exon 20 mutant NSCLC. This data is summarized below:
>
> - ***In 44 evaluable patients with EGFR exon 20 mutations, the confirmed overall response rate was 43%*** and disease control rate was 90%. Median progression free survival was 5.5 months.
> - In evaluable patients with HER2 exon 20 mutations, the confirmed overall response rate was 42% and disease control rate was 83%. Median progression free survival was 5.1 months.
> - ***EGFR-related toxicities (including rash, diarrhea and paronychia) were manageable and required dose reductions in 60% of patients***. Discontinuation due to poor tolerance was rare (approximately 3% of patients).

213. The Company's statements in ¶212 were materially false and misleading or omitted material information because it emphasized old results without disclosing more recent and reliable – but less impressive – Cohort 1 and 3 results. The reference to outdated results failed to disclose:

(a) that Pozi had just failed to demonstrate efficacy in Cohort 1. In reality, in March 2019, Spectrum had fully confirmed data showing that Pozi demonstrated only 14.8% ORR, well short of the 43% ORR the Company highlighted. Pozi had also performed far worse in terms of safety in Cohort 1, with 88% of patients requiring dose interruptions, 68% dose reductions, and 10% discontinued treatment. The Cohort 3 results, fully confirmed as of July 4, 2020, showed a 27.8% ORR, with dose interruptions occurring in 94% of patients, and discontinuation occurring in 8%.

(b) the material difference in results at a small single-center study at MD Anderson, a world-renowned cancer center with world-renowned oncologists, and results in a generalized and more representative multicenter study at a variety of centers across the world. In addition, as CW-2 explained, single-center studies allow for "unconscious biases" or incentives to "minimize, delay or not report AEs" in order to keep patients on the drug for a longer period of time. Defendants failed to disclose that Pozi would perform materially worse in Cohort 1.

214. The Company's statements in ¶212 were knowingly or recklessly false and misleading or omitted material information because by July 4, 2020, it was clear that Pozi had performed far worse in Cohort 1 and Cohort 3 than the MD Anderson trial data, demonstrating an efficacy of just 14.8% ORR and 27.8% ORR, respectively, including because:

(a) the ZENITH20 trial was open-label, which means Defendants had access to the data throughout the trial.

(b) Defendants conceded that the open nature of the ZENITH20 trial granted them access to the information as it came in. For example, on October 2, 2019, Lebel said: "[I]t is an open arm study. So, in theory ***we could look at the data*** – we could've looked at the data." And on May 7, 2020, on the Q1 2020 Earnings Call, Lebel discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "***there will be regular looking at the data***," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(c) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors:

"I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(d) Insiders confirmed that Spectrum had the data. CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics shared real-time data, including efficacy data and results, on Spectrum's EDC system. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2, a former executive director at Spectrum who worked on Cohort 1 of the ZENITH20 trial, corroborated CW-1's account that Spectrum personnel had access to the EDC system, including "efficacy graphs and safety printouts," during the ZENITH20 trial. CW-1 also had weekly meetings with Spectrum personnel, including Lebel's direct report, to discuss data, and Spectrum took minutes of these meetings. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," which the rep then "reported the information up the chain" at Spectrum. CW-2 explained: "It was the understanding when I left [in Q3 2020]" within Spectrum that Pozi would not be approved by the FDA due to the intolerable side effects and their impact on efficacy.

c. Adverse Events

Lebel

215. On the Company's Q1 2020 Earnings Call, Lebel made the following materially false and misleading statement:

> So I think you're right on here, patients who are treatment naive, like we have in cohort 3 and 4, are – one would expect that they would be able to – they're in much better condition. They have not – their bone marrow have not beaten up with rounds of chemotherapy or some other therapy like the checkpoint inhibitor, where they might have had pneumonitis or other complication. ***So one would expect that they would be more tolerant of adverse events, potentially***.

216. On the same call, Lebel made the following additional materially false and misleading statement:

> And the other thing you got to remember is that poziotinib right now, we have dosed more than 1,000 patients at different dose and schedule. Takeda is not as advanced that way. So over time here, we might uncover that there are different adverse events that are uncovered. ***And we're pretty confident right now. We understand quite well the side effect profile of pozi. We understand and we believe on the basis of the data and modeling we've done that we could mitigate the amount of adverse events we see***. And we're anxious to see the result of cohort 5 when we give the drug BID. So I guess the short answer is stay tuned. And we'll see with more data, which drug is – will come to market first and which one is more promising.

217. On November 4, 2020, during the Company's Q3 2020 Earnings Call, Lebel made the following materially false and misleading statement in response to a question from an analyst:

> [Analyst:] This is Charles Zhu on for Michael Schmidt. I had a couple regarding poziotinib. I guess starting off, the ZENITH20 cohort 3, that should be reading out by year-end. Given that this is a less heavily pretreated population relative to cohort 1, how should we think about, I guess, patient willingness or ability to tolerate poziotinib side effects at the 16-milligram dose? And what could this mean for dose interruptions, discontinuations or overall drug exposure?
>
> [Lebel:] Sure. So look, we – until we see the data and present the data and share the data with you, at least the top line data, I can't presume at this point of what we're going to see totally in the safety profile. ***Clearly, we monitor safety on all our studies, including these cohorts and for signals that would be out of the ordinary. And as you know, we have not had to make any announcement of that sort***. So we're going to have to wait for the complete analysis that – it's not that far away. We're saying you're going to have it before the end of the year.

218. Lebel's statements in ¶¶215-217 were materially false and misleading or omitted material information because he incorrectly suggested that Spectrum could attain a manageable level of adverse events in Cohort 3. Lebel's assertions that Spectrum "could mitigate the amount of adverse events we see" and that Cohort 3 adverse events were not "out of the ordinary" failed to disclose to unknowing investors that:

(a) Prior to these statements, on July 4, 2020, Spectrum had safety data showing AEs so dramatic that patients could not stay on the drug. Spectrum ultimately reported safety data even worse than Cohort 1, showing that ***94%*** of patients had dose interruptions, and 8% of patients discontinued treatment altogether. This was worse than how Pozi performed in Cohort 1, which had dose interruptions in 88% of patients. It was also worse than the moderate AEs experienced by patients taking existing TKI Tagrisso. CW-1, a researcher at a clinic for ZENITH20, recalled that

"toxicity levels were tough" in the trial and the biggest issue for patients taking Pozi. CW-1 tried to mitigate AEs with steroids and antibiotics, using "magic mouthwash" and even "butt paste," but side effects remained a major problem. CW-2, an executive director at Spectrum, confirmed that AEs were a major issue during the ZENITH20 trials, because the "16-milligram-per-day dose was far higher than what was needed, and it corresponded with bad side effects." CW-2 remembered that "85 percent of patients had serious side effects" such as rashes and diarrhea, and the AEs "were disabling, intolerable." According to CW-2, many patients who wanted to continue with the drug had to stop because the AEs were so severe.

(b) The AEs impacted Spectrum's efficacy results in the Cohort 3 trial, in which Pozi demonstrated efficacy of just 27.8% ORR, which fell short of the 30% ORR efficacy endpoint required for FDA approval. CW-1 said it was his/her understanding that Pozi failed because of "toxicity and the AEs. If the AEs had been managed better by the sites, they would have had better outcomes." CW-2 confirmed that AEs "affected the efficacy of the drug if patients dropped out."

219. Lebel's statements in ¶¶215-217 were knowingly or recklessly false and misleading or omitted material information because by July 4, 2020, it was clear that Cohort 3 demonstrated high rates of adverse events, including because:

(a) The ZENITH20 trial was open-label, which means Lebel had access to the data throughout the trial.

(b) Lebel conceded that the open nature of the ZENITH20 trial granted him access to the information as it came in. For example, on October 2, 2019, he said: "[I]t is an open arm study. So, in theory ***we could look at the data*** – we could've looked at the data." And on May 7, 2020, on the Company's Q1 2020 Earnings Call, he discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "***there will be regular looking at the data***," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(c) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors:

"I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(d) CW-1 worked at a clinical trial site and confirmed that his/her clinic and other clinics regularly shared data, including adverse events data and results, with Spectrum via the EDC database. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2 – Lebel's direct report - confirmed that Spectrum used the EDC system during the trial, and that it contained data and results collected from the clinical sites, including "efficacy graphs and safety printouts." CW-1 also said that, during the Cohort 1 trial, he/she attended weekly meetings with Spectrum personnel including Lebel's direct report, where attendees discussed safety data and Spectrum took meeting minutes. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," and the rep then "reported the information up the chain" at Spectrum. CW-2 explained: "It was the understanding when I left [in Q3 2020]" within Spectrum that Pozi would not be approved by the FDA due to the intolerable side effects and their impact on efficacy.

4. Statements Denying Access to ZENITH20 Data and Results

220. Defendants falsely and misleadingly told investors they were not looking at data and results from the ZENITH20 trial.

Lebel

221. At the October 2, 2019 Cantor Fitzgerald Global Healthcare Conference, Lebel made the following materially false and misleading statements:

> We are going to have to wait for the data so that people understand why is it that I don't know the data. So, the reason, it is an open arm study. ***So, in theory we could look at the data – we could've looked at the data.***
>
> ***We decided at the Company that we did not want to look at the data***. We wanted to make sure that there's a central imaging lab. They are not influenced by what potentially investigators, etc., would know. And also, we've also put in an independent data review committee, meaning expert lung cancer specialists were going to look at the data before we get to look at the data in the central imaging lab.

> So, that will allow us – for us to – ***nobody is looking at the data for six months***. The last patient in, the first time that we're going to look at the data will be after six month's follow-up minimum.
>
> What that will allow us to do is that whenever we turn the card and we announce, okay, here is the top level response rate. We at that time would know also that it's somewhat durable response because you will have at least six months of data to look at. ***As opposed to announce early and then have to retract later that we had great response but wasn't clinically meaningful and didn't last***.

222. Lebel's statements in ¶221 were materially false and misleading or omitted material information because he incorrectly suggested that Spectrum did not look at ZENITH20 data. Lebel's assertions that Spectrum "decided at the Company that we did not want to look at the data" failed to disclose to unknowing investors that Spectrum was fully apprised of efficacy and safety data as the ZENITH20 trial progressed.

223. Lebel's statements in ¶221 were knowingly or recklessly false and misleading or omitted material information because by March 2018, Spectrum routinely looked at the data, including because:

(a) The ZENITH20 trial was open-label, which means Lebel had access to the data throughout the trial, which started in October 2017.

(b) Lebel conceded that the open nature of the ZENITH20 trial granted them access to the information as it came in. For example, on May 7, 2020, on the Company's Q1 2020 Earnings Call, he discussed how ZENITH20 is a "an open trial," and that in the upcoming Cohort 5 "***there will be regular looking at the data***," such that "[w]e will be able to get some insight, gain insight before we fully enroll."

(c) Defendants spoke about data before it was public. On the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." And on August 10, 2020, Lebel said: "Obviously, we're looking at data. It's an open-label study."

(d) Insiders confirmed that Spectrum had the data. CW-1 worked at a clinical trial site until March 2018 and confirmed that his/her clinic and other clinics shared real-time data, including efficacy data and results, on Spectrum's EDC system. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call CW-1 on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-2, a former Executive Director at Spectrum who worked on Cohort 1 of the ZENITH20 trial and reported directly to Lebel, corroborated CW-1's account that Spectrum personnel had access to the EDC system, including "efficacy graphs and safety printouts," during the ZENITH20 trial. CW-1 also had weekly meetings with Spectrum personnel, including Lebel's direct report, to discuss data, and Spectrum took minutes of these meetings. Also, once per month, a "rep" from Spectrum visited the clinical trial site to look at data from "each chart for each patient," which the rep then "reported the information up the chain" at Spectrum.

B. Statements Concerning Rolontis

1. BLA Withdrawal "Voluntary"

224. Defendants incorrectly told investors Spectrum chose to "voluntarily" withdraw their BLA, when in reality Spectrum was forced to withdraw the application in order to avoid a CRL from the FDA rejecting the Rolontis application. For additional indicia of scienter beyond that listed below, *see* §VII, *infra*.

Turgeon

225. On September 11, 2019, during the 2019 Morgan Stanley Conference, Turgeon made the following materially false and misleading statements:

> [Analyst:] There was an initial filing put in late last year, and it was pulled back as manufacturing. Could you elaborate on that?
>
> [Turgeon:] Yes, we made the decision. I'll walk you down memory lane. What happened was we filed – and I think it was 22nd of December last year. And what happened was that we had – the government had shut down, so we didn't hear anything from the agency. So the clock started ticking on the 60 days after they got back to at the end of January.

> So about 2 weeks before the end of March, we had a meeting with the agency, and they said "By the way, we have an issue with the CMC portion. We had 2 weeks left until the 60 days were up." And I said, "***We need some additional information, nothing that was over the top, but we need this information." And we have formatting issues. We had a lot of translation because a lot of it was done in Korea, and they didn't like the way we were translating things. We had to reformat some of the tabling and things***.
>
> So the bottom line is, we had to get some additional information. We knew we couldn't do it by the 29th of March. ***So we said***, "***Why don't we voluntarily – we'll pull it." Then they said, "Fine," without prejudice***. They said, "We'll give you exactly what we want." ***We've since met with them. They gave it to us, and I'm happy to tell you we're in good shape to launching – to submit it in the fourth quarter***.

226. On November 7, 2019, during the Company's Q3 2019 Earnings Call, Turgeon made the following materially false and misleading statement:

> [Turgeon:] ROLONTIS is our late-stage drug being developed for the treatment of chemotherapy-induced neutropenia. ***As you recall, we voluntarily withdrew our BLA application earlier this year***. Since then, we worked closely with the FDA and recently submitted a robust package. We look forward to competing in this market.

227. Turgeon's statements in ¶¶225-226 were materially false and misleading or omitted material information because he incorrectly suggested that the Company chose to withdraw the Rolontis BLA on March 15, 2019. Turgeon's assertions that Spectrum independently decided to "voluntarily" withdraw the BLA failed to disclose that the FDA had given them an ultimatum: withdraw the BLA or it will be rejected.

228. Turgeon's statements in ¶¶225-226 were knowingly or recklessly false and misleading or omitted material information because at the time Spectrum withdrew the BLA on March 15, 2019, it was clear that Spectrum had not done so voluntarily. Turgeon later admitted that the FDA had given Spectrum an ultimatum. After the Class Period, on August 12, 2021, he said: "So, they [the FDA] told us, look[,] in this form we wouldn't accept it, so you can wait for us to not accept that or you could voluntarily fix this stuff and resubmit. And that's what happened."

The Company

229. In a press release dated March 15, 2019, the Company made the following materially false and misleading statements:

> Spectrum Pharmaceuticals announced due to the U.S. Food and Drug Administration's (FDA) request for additional manufacturing-related information for ROLONTIS, ***the company has voluntarily withdrawn its Biologics License Application (BLA)***. Spectrum plans to resubmit a revised BLA as soon as possible.
>
> The FDA did not cite concerns related to the pre-clinical and clinical modules of the BLA or the need for additional clinical studies. ***Spectrum's decision to withdraw the BLA*** was the result of the company needing more time to provide certain additional manufacturing-related information, which was required before March 29, 2019, the day that the FDA's initial 60-day review period ends.

230. Spectrum's Form 10-Q filing filed with the SEC on May 9, 2019 contained signed certifications from Turgeon and Gustafson attesting, among other things, that:

> Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

In the filing, Spectrum made the following materially false and misleading statement:

> We submitted our Biologics License Application ("BLA") with the FDA in December 2018. In March 2019, ***we voluntarily withdrew this BLA*** due to the FDA's request for additional manufacturing-related information for ROLONTIS and the time required to complete this documentation. However, the FDA did not cite concerns related to the pre-clinical and clinical modules of the BLA or the need for additional clinical studies. We plan to resubmit a revised BLA as soon as possible.

231. Spectrum's Form 10-Q filed with the SEC on August 9, 2019 contained signed certifications from Turgeon and Gustafson attesting, among other things, that:

> Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

In the filing, Spectrum made the following materially false and misleading statement:

> We submitted our Biologics License Application ("BLA") with the FDA in December 2018. However, in March 2019, ***we voluntarily withdrew this BLA*** due to the FDA's request for additional manufacturing-related information for ROLONTIS that requires our additional documentation. The FDA did not cite concerns related to the pre-clinical and clinical modules of the BLA or the need for additional clinical studies. We continue to update this BLA and expect to submit a revised filing during the fourth quarter of 2019.

232. Spectrum's Form 10-Q filing filed with the SEC on November 7, 2019 contained signed certifications from Turgeon and Gustafson attesting, among other things, that:

> Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

In the filing, Spectrum made the following materially false and misleading statement:

> We submitted our updated Biologics License Application ("BLA") for ROLONTIS with the FDA on October 24, 2019. In March 2019, ***we voluntarily withdrew our December 2018 BLA*** for ROLONTIS due to the FDA's request for additional information in the Chemistry, Manufacturing, and Controls (CMC) section. Our BLA is supported by data from two identically designed Phase 3 clinical trials, ADVANCE and RECOVER, which evaluated the safety and efficacy of ROLONTIS in 643 early-stage breast cancer patients for the treatment of neutropenia due to myelosuppressive chemotherapy.

233. The Company's statements in ¶¶229-232 were materially false and misleading or omitted material information because Defendants incorrectly suggested that the Company chose to withdraw the Rolontis BLA on March 15, 2019. The Company's assertions that Spectrum independently decided to "voluntarily" withdraw the BLA failed to disclose that the FDA had given them an ultimatum: withdraw the BLA or it will be rejected.

234. The Company's statements in ¶¶229-232 were knowingly or recklessly false and misleading or omitted material information because at the time Spectrum withdrew the BLA on March 15, 2019, it was clear that Spectrum had not done so voluntarily. Turgeon later admitted that the FDA had given Spectrum an ultimatum. After the Class Period, on August 12, 2021, he said: "So, they [the FDA] told us, look[,] in this form we wouldn't accept it, so you can wait for us to not accept that or you could voluntarily fix this stuff and resubmit. And that's what happened."

2. Readiness for FDA Inspection of Hanmi

235. Defendants made false and misleading representations about their readiness for the FDA's inspection of the Hanmi manufacturing facility in South Korea, without disclosing that it fell well below FDA standards, and that Spectrum did not have the power or influence to bring it into compliance. For a timeline of FDA inspection events and statements, *see* Appendix D attached hereto. For additional indicia of scienter beyond that listed below, *see* §VII, *infra*.

Turgeon

236. On November 4, 2020, during the Company's Q3 2020 Earnings Call, Turgeon made the following materially false and misleading statements:

> Regarding the ROLONTIS plant inspection, our partner, Hanmi Pharmaceuticals, is a well-established global biopharmaceutical player with a world class manufacturing facility. Hanmi is the second largest pharmaceutical company in Korea, behind only Samsung. ***They're prepared for the inspection*** and willing to be accommodative to the needs of the FDA as it strives to meet the regulatory obligations. ***They've been a great partner and are working in tandem with Spectrum to obtain an approval for ROLONTIS as soon as is possible***.
>
> * * *
>
> And I want to stress another thing. ***We are absolutely ready for this inspection. We've been ready for a long time. We welcome it***. As a matter of fact, the third part of your question was the mock inspections, was it required? They're certainly not required by the agency. ***We do that to make sure we're ready. And I can tell you, we have Spectrum boots on ground there***. We have Hanmi, which I mentioned, is a world-class manufacturer with a world-class plant. ***There are people already, and we work very closely with them with these mock inspections***.
>
> And we have a third leg to the stool. ***We have outside experts we've hired to run these – not only run these mock inspections, but also help the readiness. And these are people who have done this for a living. They do this – they know exactly what people – what the FDA is looking for an inspection. So we feel we're ready. We welcome the inspection and we can't wait***.

237. On December 22, 2020, Spectrum held a special conference call to address investors and analysts regarding the devastating Pozi news. On that call, Turgeon made the following materially false and misleading statements concerning Rolontis:

> I can't give you an exact date when it will be inspected. But I'm going to tell you, ***we're ready***.
>
> The facility has been through ***multiple mock inspections***. It's ***kind of like the army now*** is what I say, we're still going through the drill on a weekly basis, still doing the mock inspections, getting ready for any questions we might get. We have ***Spectrum people on the ground at the plant***. We have, of course, Hanmi people who are very well prepared, been working with us, and we have third-party experts there working for the readiness. So ***we really feel we're ready for this inspection***.

238. On May 13, 2021, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q1 2021 results. During the call, Turgeon made the following materially false and misleading statement:

> The FDA scheduled the pre-approval inspection of our manufacturing facility for later this month. We believe this inspection marks the final step in the approval process, and that ***Hanmi's world-class facility is ready for this inspection***.

239. Later on the same call, Turgeon continued:

> Yes, we don't know the exact timing, but let's go back in time where we, as you recall, and I know you well know, we received a deferral back in ***our PDUFA date – back in October, not a CRL, which – clearly if there were problems like many other companies got with our clinical data, we feel we would have gotten the CRL. We didn't***. But because of the pandemic, we couldn't get people to South Korea to do the file. And I know you know all of that. ***We're prepared for the inspection. We're looking forward to it***. I can't give you an exact date, but I think the FDA would take a reasonable amount of time to get back to us once the inspection is done and we feel that's the last step. So without giving an exact time, I think it'll be a reasonable amount of time after the inspection is done.

240. Turgeon's statements in ¶¶236-239 were materially false and misleading or omitted material information because he recklessly and incorrectly described the Company as "ready for the inspection" and made misleading claims that Spectrum retained "outside experts" to run "mock inspections" to ensure compliance with FDA guidance. In reality, the Rolontis manufacturing facility maintained controls and procedures that deviated substantially from FDA requirements. As CW-2 described, although Spectrum wanted to supervise procedures at the Rolontis factory in South Korea, in reality Spectrum did not have control over what happened at Hanmi. As for the mock inspections, CW-2 disclosed that Spectrum "***failed [the mock inspections] a couple of times***." This is because, according to CW-2, "the quality of plants and people [at Hanmi] were not up to industry standards." Ultimately, when the FDA inspected plant, it found ***ten independent deficiencies***, including "equipment failures," "[p]rocess understanding is deficient," "[d]ocumentation for cleaning procedures . . . deficient," and "[c]onformance to the submitted application is inadequate."

241. Turgeon's statements in ¶¶236-239 were knowingly or recklessly false and misleading or omitted material information because prior to Turgeon's first statement on November 4, 2020, it was clear that Hanmi was not prepared for the FDA inspection, including because:

(a) By the end of 2019, he repeatedly expressed intimate knowledge regarding the FDA's expectations and requirements for the manufacturing facility. For example, on May 9, 2019, Turgeon said: "***[W]e're working diligently to prepare the CMC module. I'll remind you, they told***

us exactly what they want. They're working with us, being very helpful." And on August 8, 2019, he again said: "Listen, ***we are aligned with the FDA***. We had our meeting. We got aligned." On October 2, 2019, Turgeon said: "[W]e did have a positive meeting with the agency where they walked us through. We wanted to make sure we knew exactly what they wanted in the CMC section. . . . ***I think we are going to have everything they want and then some***."

(b) By the end of Q3 2020 (September 30, 2020), when CW-2 left the company, Spectrum had already failed multiple mock inspections. CW-2 explained that these failures were "common knowledge" at Spectrum.

(c) The deficiencies were so serious and widespread, that adequate mock inspections would have caught them. As the FDA found when it inspected the plant from May 25, 2021 through June 2, 2021, Hanmi had deficient "equipment," "[p]rocess understanding," "[d]ocumentation for cleaning procedures," and "[c]onformance to the submitted application," among other things.

(d) On March 15, 2021 and March 16, 2021, Turgeon sold over 68,000 shares (his second-largest sale ever) for nearly $250,000 in proceeds.

Lebel

242. On November 4, 2020, during the Company's Q3 2020 Earnings Call, Lebel made the following materially false and misleading statement:

> As to the deferred action on our ROLONTIS filing, we have answered all questions from the FDA related to the review of the BLA, and we've had advanced labeling discussions. ***On the manufacturing side, we have conducted multiple mock inspections of our plant and are exploring ways to expedite the inspection, possibly using alternative methods to ensure the earliest completion of the review of our BLA during this COVID-19 pandemic***. We look forward to updating you on important program milestone in the next 2 months including the outcome of our poziotinib registration discussion with the FDA.

243. On March 30, 2021, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q4 2020 results. During the call, Lebel made the following materially false and misleading statement:

> Regarding the deferred action on our ROLONTIS filing that Joe mentioned, we believe that we have answered satisfactorily all questions from the FDA related to

> the review of the BLA. And we believe that the inspection represents the final step in the review process. ***We and our partner, Hanmi, are ready for the FDA pre-approval plant inspection that has been scheduled for May***.

244. On May 13, 2021, Spectrum hosted an earnings call with investors and analysts to discuss the Company's Q1 2021 results. During the call, Lebel made the following materially false and misleading statement:

> Now let me shift to ROLONTIS. On the regulatory side, Joe has already updated you on the status of the pre-approval inspection, and ***we remain confident that our preparation with our partner Hanmi, should result in a positive outcome for this FDA plant inspection***.

245. Lebel's statements in ¶¶242-244 were materially false and misleading or omitted material information because he recklessly and incorrectly described the Company as "ready for the FDA pre-approval plant inspection" and made misleading claims that Spectrum conducted "multiple mock inspections" to ensure compliance with FDA guidance. In reality, the Rolontis manufacturing facility maintained controls and procedures that deviated substantially from FDA requirements. As CW-2 (Lebel's direct report) described, although Spectrum wanted to supervise procedures at the Rolontis factory in South Korea, in reality Spectrum did not have control over what happened at Hanmi. As for the mock inspections, CW-2 disclosed that Spectrum "***failed [the mock inspections] a couple of times***." This is because, according to CW-2, "the quality of plants and people [at Hanmi] were not up to industry standards." Ultimately, when the FDA inspected plant, it found ***ten independent deficiencies***, including "equipment failures," "[p]rocess understanding is deficient," "[d]ocumentation for cleaning procedures . . . deficient," and "[c]onformance to the submitted application is inadequate."

246. Lebel's statements in ¶¶242-244 were knowingly or recklessly false and misleading or omitted material information because prior to Lebel's first statement on November 4, 2020, it was clear that Hanmi was not prepared for the FDA inspection, including because:

247. By the end of 2019, he repeatedly expressed intimate knowledge regarding the FDA's expectations and requirements for the manufacturing facility. For example, on August 8, 2019 Lebel said: "***[W]e recently had a productive meeting with the FDA to further discuss their expectation around module 3***." On November 7, 2019, he said: "[W]e've had productive dialogue with the

FDA. ***We implemented their guidance***, provided additional data and rewrote and reorganized certain sections of the file resulting in a strong submission."

(a) By the end of Q3 2020 (September 30, 2020), when CW-2 left the company, Spectrum had already failed multiple mock inspections. CW-2 explained that these failures were "common knowledge" at Spectrum.

(b) The deficiencies were so serious and widespread, that adequate mock inspections would have caught them. As the FDA found when it inspected the plant from May 25, 2021 through June 2, 2021, Hanmi had deficient "equipment," "[p]rocess understanding," "[d]ocumentation for cleaning procedures," and "[c]onformance to the submitted application," among other things.

(c) On March 15, 2021 and March 16, 2021, Lebel sold over 41,000 shares (largest sale ever, 18.6% of his holdings) for over $150,000 in proceeds. Lebel's sale was his largest ever.

VII. ADDITIONAL ALLEGATIONS IN SUPPORT OF SCIENTER

A. Defendants and Other Spectrum Insiders Repeatedly Expressed Defendants' Knowledge of Material Information Indicating Their Statements Were False and/or Misleading

248. Throughout the Class Period, Defendants frequently discussed and held themselves out as knowledgeable about material information directly related to the prospects for the Pozi clinical trials and the Rolontis BLA inspection. Confidential witnesses have corroborated Defendants' use of and access to this information.

249. With respect to Pozi, Defendants repeatedly acknowledged their access to data from the MD Anderson and ZENITH20 trials well in advance of the disclosure of final results from those studies. For example, on the Company's Q1 2018 Earnings Call on May 3, 2018, Riga expressed keen familiarity with the data from the MD Anderson trial, saying: "As we evaluate the criteria for breakthrough therapy designation, we believe that pozi meets the criteria ***if the early data continues***." On the same date, Turgeon said: "***I'm feeling pretty good about the early data when you look at that***. How can you not?" And for ZENITH20, on May 16, 2018, Turgeon told investors: "I got an update yesterday on the enrollment [of the ZENITH20 trial]." On August 9,

2018, Riga said: "We've seen very strong early data in an area of high unmet medical need. ***We have alignment with the agency on our Phase II trial*** . . . ." And on May 7, 2020, on the Company's Q1 2020 Earnings Call, Lebel discussed how ZENITH20 is a "an open trial," which means "***there will be regular looking at the data***," such that "***[w]e will be able to get some insight, gain insight before we fully enroll***."

250. Accounts from insiders confirmed that Defendants had access to trial data at the time they made the false and misleading statements discussed *supra* §VI. For example, CW-1 described in detail how he/she and others who worked at his/her clinical trial site input data on the EDC system. According to CW-1, Spectrum controlled the EDC system and had access to the information stored on it in real time. CW-1 knew people at Spectrum saw the data during the ZENITH20 trial because Spectrum employees would directly call him/her on an ad hoc basis with "inquiries" about the data that CW-1 had entered. CW-1 said he/she "got phone calls from a whole bunch of people at Spectrum" and that the calls happened "throughout the trial." CW-1 added that he/she was "pretty sure that higher-level people could see it," as he/she was not aware of any restrictions that prevented executives from accessing the database. CW-2 confirmed that Spectrum used an EDC system that contained data and results collected from the clinical sites, including "efficacy graphs and safety printouts." The data stored on the EDC, CW-2 continued, was available to Spectrum personnel throughout ZENITH20. CW-2 also described how Lebel referenced data from the trials in Spectrum meetings before it was disclosed to the public. For example, CW-2 explained that Lebel knew by Q2 2019 – before results were public – that "the Pozi dose was too high" for patients to tolerate. Additionally, CW-2 said that open trials like ZENITH20 had fewer restrictions than blinded trials regarding who at the company had access to data.

251. Defendants also consistently held themselves out as knowledgeable about the clinical trial data, including the AEs caused by the high dosage of Pozi in the ZENITH20 trial when market research analysts asked for updates. For example, on the Company's Q3 2018 Earnings Call on November 8, 2018, Turgeon directly addressed the AEs associated with Pozi, saying: "***[W]hile the rash was, as I believe, that's 34%, it was manageable. It's what we heard from the site. It's not***

that different than other TKIs." Riga added: "***[T]he management of very TKI-like side effects is something that the sites are equipped to do***."

252. Evidence from confidential witnesses and the FDA Briefing Document released prior to the Oncologic Drugs Advisory Committee Meeting in September 2022 (the "FDA Briefing Document") corroborate that Defendants were well aware of the severity of the AEs associated with the ZENITH20 trial throughout the Class Period. For example, CW-2, who Lebel made the "point person to manage the side effects from Poziotinib," confirmed that by the time he/she started at Spectrum, Lebel already knew that "the Pozi dose was too high" for patients to tolerate. CW-2 said Lebel described his concern about the high dosage "in several meetings with other people there," including CW-2. CW-2 recalled that Lebel "said crystal clear that the dose was too high. But he wouldn't do a new PK study – a pharmacokinetic study" to trial a lower dose of Pozi "because that would slow the whole program down."

253. Moreover, the FDA Briefing Document revealed that as early as July 28, 2017, the FDA had communicated its concerns to Spectrum that the ZENITH20 trial would not identify a dosage of Pozi that provided the optimal balance of efficacy and safety needed to maximize the chances of a successful outcome in subsequent trials. Lebel ultimately acknowledged on May 7, 2020, that: "We now believe that the 16-milligram once-daily dose might have been too wide to administer all at once and led to frequent dose interruptions and dose reductions. 88% of patients had some sort of dose interruption from therapy, which we believe prevented the drug from demonstrating its full potential."

254. Spectrum executives also repeatedly emphasized their close working relationship with FDA officials and their personal knowledge about the FDA's requirements for Pozi to obtain BTD status and, ultimately, to be approved for use in the United States. For example, on the Company's Q4 2017 Earnings Call on March 6, 2018, just weeks before the start of the Class Period, Riga admitted: "[W]e are having ongoing dialogue with the FDA to find the most-expedient regulatory pathway" for Pozi, and Turgeon said, "[w]e've done extensive research on – and our homework on what it takes for breakthrough therapy." On August 9, 2018, Riga said: "So we have established a really good rapport with the agency on this program on a number of levels because of the unmet

need and I've been pleased with the level of interaction and how our team is prepared." Later in the call, he said: "***We've seen very strong early data in an area of high unmet medical need. We have alignment with the agency on our Phase II trial*** . . . ." On November 8, 2018, on the Company's Q3 2018 Earnings Call, in response to a question from an analyst regarding the Pozi BTD application, Turgeon said: "We ***knew exactly . . . what [the FDA] wanted***, and I think we gave them the data they asked for." On December 19, 2018, Riga told investors: "***I actually participated in the Type C meeting with the agency. We had very productive discussions on the trial design and the subsequent minutes give us high confidence that we are well positioned to have a registrational study***." With respect to the ZENITH20 trial, on February 28, 2019, during an earnings call with investors and analysts to discuss the Company's Q4 2018 results, Lebel admitted that "we've had discussion with the FDA. ***There's an agreement, full understanding of what we need to meet***."

255. Defendants made similar statements with respect to the Rolontis BLA. For example, on May 9, 2019 during an earnings call with investors and analysts to discuss the Company's Q1 2019 results, Turgeon stated: "I'll remind you of this: ***we're working diligently*** to prepare the CMC module. I'll remind you, ***they told us exactly what they want***. They're working with us, being very helpful." On the Company's Q2 2019 Earnings Call on August 8, 2019, Lebel stated: "Regarding our BLA filing, ***we recently had a productive meeting with the FDA to further discuss their expectation*** around module 3, which is the module focused on manufacturing." And on November 4, 2020, Turgeon told investors: "[W]e update with the Hanmi team quite often." On the same call, when asked about what "cadence of discussions" Spectrum was having with the FDA, Lebel responded: "I'm not going to get into the details of how many communication, et cetera. But ***clearly, we're working closely with them***."

256. A former employee has indicated that Defendants knew that the Hanmi plant did not measure up to the FDA's inspections. CW-2 said it was "common knowledge" by Q3 2020 that Hanmi "failed [the mock inspections] a couple of times." This is because "the quality of plants and people [at Hanmi] were not up to industry standards."

257. Defendants repeated statements with respect to the Pozi trials and the Rolontis BLA during the Class Period indicate their awareness of, and focus on, issues with respect to meeting the

efficacy, safety, and manufacturing requirements from the FDA. These statements are all highly indicative of Defendants' scienter.

B. Defendants Engaged in Insider Trading

258. The Individual Defendants were motivated to engage in the alleged fraud and artificially inflate the price of Spectrum common stock to make millions of dollars in insider sales.

259. The Individual Defendants capitalized on the fraud by selling unusually large amounts of their holdings at suspicious times during the Class Period. The amount and timing of their sales supports a strong inference that they timed their respective trading with knowledge of the alleged fraud and sought to capture the stock's artificially inflated trading price before the market learned of the truth concealed by the fraud. For example, between March 25, 2019 and April 1, 2019, Gustafson sold over 15,000 shares, collectively his second-largest open-market sale ever, for nearly $159,000 in proceeds. On May 16, 2019 and June 6, 2019, Turgeon collectively sold over 40,000 shares – totaling approximately 9% of his available holdings – for nearly ***$340,000*** in proceeds. At the time of these sales, Defendants had access to full responsiveness data from every participant in Cohort 1 of the ZENITH20 trial, which demonstrated Pozi would fail that portion of the trial.

260. Also, several of the Individual Defendants' sales occurred immediately prior to disclosures that revealed partial truths about the deficiencies of Pozi and Rolontis. For example, throughout 2019, Lebel evinced baseless optimism for the results of Cohort 1 and told investors that Pozi's safety profile was "in line" with other EGFR TKIs. Contrary to his rosy assertions regarding Cohort 1, on November 6, 2019, Lebel made his first sale ever of 6,963 shares of Spectrum common stock for $56,818 in proceeds. Merely weeks later, on December 26, 2019, the Company announced that Pozi did not meet its pre-specified endpoint in Cohort 1 of ZENITH20.

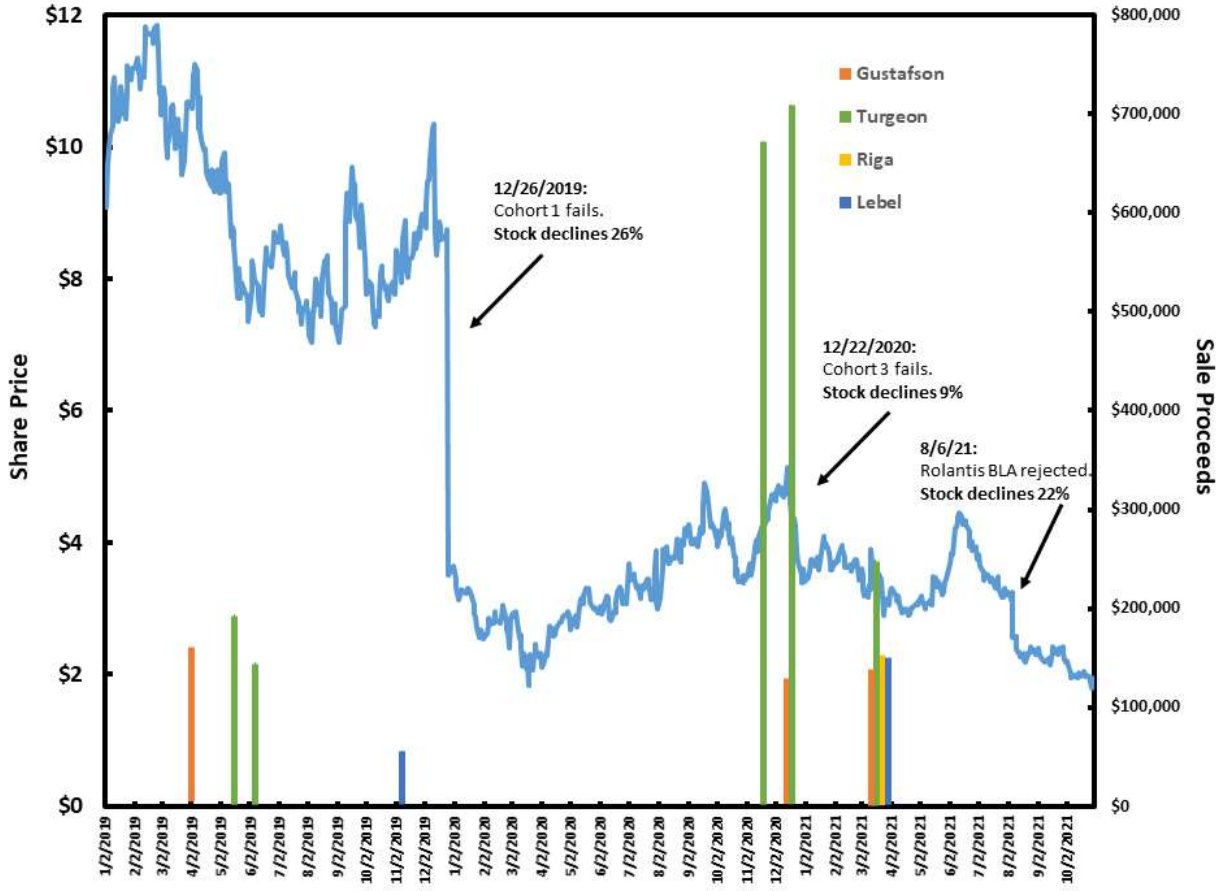
261. Similarly, on November 4, 2020, Turgeon pumped Spectrum's stock price by feigning confidence about the disappointing data on the Company's Q3 2020 Earnings Call, when he stated: "I'm really confident in our ability to meet our corporate objectives and advance our programs with the aspiration of bringing new treatments to the patients with cancer who need it." In contrast with that positive outlook, both Turgeon and Gustafson began rapidly dumping their

Spectrum holdings. On November 18, 2020, Turgeon sold 162,473 shares of Spectrum common stock for a $671,013 in proceeds. Those shares represented 23.5% of Turgeon's holdings at the time. Shortly thereafter, on December 14, 2020, Gustafson sold 25,696 shares (7.1% of his holdings) for proceeds of $128,480. Two days later, on December 16, 2020, Turgeon sold 150,899 more shares, 28.54% of his remaining holdings, for proceeds of $709,225. In total, Spectrum's CEO had offloaded almost half of his Spectrum holdings, for proceeds of almost $1.4 million.

262. Just days after Turgeon and Gustafson pocketed massive profits from Spectrum's inflated stock price, on December 22, 2020, they and the other Spectrum executives disclosed that data from the ZENITH20 Cohort 3 study had failed to meet the primary endpoint – information that Defendants had been aware of for months before this disclosure, yet concealed from investors. The disappointing news drove the Company's stock price downward by 9.1%.

263. Regarding Rolontis, despite previously touting Hanmi's readiness for the FDA's inspection, Defendants immediately began dumping their shares. On March 16, 2021, Turgeon announced "the FDA informed us that they will be conducting a pre-approval inspection of the ROLONTIS manufacturing facility in May." On March 15, 2021 and March 16, 2021, all four Individual Defendants sold unusually large amounts of shares. Turgeon sold over 68,000 shares (his second-largest sale ever) for nearly $250,000 in proceeds; Gustafson sold over 36,000 shares (largest sale ever) for over $134,000 in proceeds; Riga sold over 42,000 shares (second-largest sale ever) for over $154,000 in proceeds; and Lebel sold over 41,000 shares (largest sale ever, 18.6% of his holdings) for over $150,000 in proceeds. Lebel's sale was his largest ever.

264. The following chart shows the timing and size of Defendant's insider sales relative to the alleged disclosures:



265. Finally, Defendants' sales are suspicious because they made substantial sales during the Class Period, but none of the Individual Defendants sold ***any*** Spectrum common stock prior to the Class Period, as shown in the chart below:

Defendant[11]	Total Proceeds from Sales Pre-Class Period	Total Proceeds from Sales During Class Period
Turgeon	$0	$3,036,796
Gustafson	$0	$1,066,194
Riga	$0	$1,206,675

C. The Fraud Implicated Spectrum's Core Products and the Individual Defendants Are High-Level Executives Who Were Directly Involved in Spectrum's Operations

266. At all relevant times during the Class Period, Spectrum was a relatively small company with less than 250 employees, with an even smaller, tight-knit upper management team. Moreover, the Individual Defendants were highly sophisticated and were Spectrum's highest-level

[11] Lebel is not included in this chart, as he did not work at Spectrum prior to the Class Period.

executives. Thus, the Individual Defendants were responsible for, and remained well informed of, issues critical to the Company's success.

267. Turgeon joined the Company in October 2012. Five years later, Spectrum appointed him as President and CEO. Commenting on Turgeon's transition to CEO in December 2017, the Chairman of Spectrum's Board noted that Turgeon "[brought] more than 30 years of experience in the pharmaceutical industry . . . . He had served as Spectrum's President and Chief Operating Officer since April 2014, and had previously served as the Company's Senior Vice President and Chief Commercial Officer from October 2012 to April 2014." Turgeon touted his professional experience to investors on September 11, 2019 at the Morgan Stanley Healthcare Conference when he said: "By the way, I have a lot of experience in this market. I was involved in the launch of the first 2 products and worked there for many years, so I know a lot about this market, but as do other people who work here."

268. Spectrum named Gustafson CFO in June 2013. Upon his arrival, the Company highlighted his "'20 years of experience in finance'" and called him "'a key addition to our already strong management team.'"

269. Lebel joined Spectrum as CMO in November 2018. At the beginning of his tenure, Turgeon described Lebel as focusing on "'several near-term milestones and priorities including expanding the development of Pozi in broader patient populations, gaining regulatory clarity for breakthrough designation on Pozi, and filing the Rolontis BLA in the fourth quarter.'" CW-2, who reported directly to Lebel, said working at Spectrum was "like the army," and the c-suite's approach to management was, "do what you're told. Your manager is god." CW-2 described Lebel, his boss, as "very controlling," noting that the understanding among his peers was "don't question Francois." This hands-on and imposing management style creates the inference that Lebel kept a keen eye on business operations.

270. Spectrum named Riga COO in December 2017. Following the Class Period, Spectrum named Riga CEO in December 2021, at which time he also joined the Company's Board. Commenting on Riga's assent to CEO, Spectrum's Chairman of the Board stated: "'We welcome Tom as the new CEO of Spectrum and look forward to the continued benefits of his entrepreneurial

and executive experience as we work to progress our two lead product candidates to commercialization.'" A press release published on December 1, 2021 stated: "Mr. Riga has over 20 years of pharmaceutical leadership experience and has demonstrated a record of success . . . . He has led multiple product launches in the oncology market, delivering innovative cancer care while establishing world class partnerships with key industry stakeholders."

271. The materially false and misleading statements and omissions detailed herein could not have occurred without the Individual Defendants' knowledge and approval because the success of Spectrum's efforts to receive FDA approval of Pozi and Rolontis were core to the Company's success.

272. First, the alleged fraud involves the most important assets Spectrum owned during the Class Period. Indeed, on the Company's Q4 2017 Earnings Call on March 6, 2018, just before the Class Period, Riga unequivocally stated: "The focus of our operations in 2018 will be surrounded by 2 main drivers: advancing the development of poziotinib and Rolontis." As the Class Period progressed, Spectrum poured more and more of its resources into developing Pozi and Rolontis. Then, on January 17, 2019, Spectrum entered into an agreement to sell its portfolio of seven FDA-approved hematology/oncology products – ***all of its other assets*** except for Pozi and Rolontis – to Acrotech Biopharma. When the Company announced the sale, Turgeon explained: "The reason we're making this strategic shift is to focus on our late-stage assets: poziotinib and ROLONTIS." This strategy persisted throughout the Class Period. On Spectrum's Q3 2019 Earnings Call, Turgeon told investors: "Our focus is crystal clear. We're developing 2 late-stage assets and expanding the pipeline." Similarly, in the Company's Q3 2020 Earnings Call, Lebel reiterated Turgeon's sentiment: "[W]e're obviously very focused on our late assets." Accordingly, the strongest inference to draw from the Company's singular focus on Pozi and Rolontis is that the Individual Defendants were fully aware of the status of all material matters involving Pozi and Rolontis.

273. Second, both Pozi and Rolontis were in development, and thus could not earn revenue for the Company. As Spectrum admitted in its 2020 Form 10-K filing with the SEC, the Company "[would] not generate any future revenue until our pipeline products, including the late-stage development products [Rolontis] and poziotinib, are approved for commercial sale by the FDA

and/or other regulatory agencies." CW-2 described that Spectrum's management was under "tremendous pressure" during his/her tenure to get a drug approved. He/she said Spectrum's "senior leadership was struggling to maintain the confidence of the board. They [would] do anything to get a drug to market" because the Company needed new lines of revenue. When discussing his/her work on Pozi, CW-2 added: "The survival of the Company depended on the drug getting approved." That the Company's financial welfare depended entirely on the distant prospect of commercializing Pozi and Rolontis during the Class Period further demonstrates the Individual Defendants' scienter.

274. Finally, the scienter of the Individual Defendants is imputable to the Company, as the misrepresentations and omissions of Spectrum, as alleged herein, were of such a nature that they would have been approved by corporate officials sufficiently knowledgeable about the Company to know that those statements and omissions were false and misleading.

D. Turgeon and Gustafson Abruptly Depart the Company

275. The unexpected departures of CEO Turgeon and CFO Gustafson shortly after the end of the Class Period bolster an already compelling inference of scienter. Turgeon "retired" on December 1, 2021, less than four years after taking over as CEO, and Gustafson followed shortly thereafter on February 23, 2022. These departures were entirely unforeseen and the Company never provided a benign reason for the sudden exodus. Rather, Spectrum released opaque statements regarding the departures such as "[we] would also like to thank [Turgeon] for his many contributions to the company," and that Gustafson had "provided notice of his resignation to pursue other professional opportunities." These same two executives made massive and uncharacteristic sales of Spectrum common stock in the days leading up to Spectrum's announcement that Cohort 3 had failed. The abrupt and unceremonious departures of the Company's most senior executives from the Company just months after the truth was revealed to the market underscores Turgeon's and Gustafson's culpability in the fraud.

E. Defendants Signed Sarbanes-Oxley Certifications Attesting They Personally Supervised Spectrum's Controls and Procedures

276. The Sarbanes-Oxley certifications signed by defendants Turgeon and Gustafson throughout the Class Period further evidence their scienter. Within the Company's Forms 10-K and

10-Q filed with the SEC by Spectrum during the Class Period, Turgeon and Gustafson certified that they were "responsible for establishing and maintaining disclosure controls and procedures" and that such controls and procedures were designed "to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared." Turgeon's and Gustafson's certifications support an inference that they knowingly or recklessly misled the market by making such representations and executing such certifications because they were at the time aware of or recklessly disregarded the truth regarding their fraudulent conduct.

F. Spectrum's Intra-Class Period Financings Incentivized Fraud

277. Throughout the Class Period, Spectrum burned through its cash reserves attempting to convince investors that the FDA would eventually approve Pozi and Rolontis. As its stockpile of money dwindled, and their two assets demonstrated that they would not reach market or start earning revenue in the near term, it became clear that Spectrum would need to raise capital through investors in order to survive.

278. During the Class Period, Defendants initiated three ATM offerings: one from April 5, 2019 to March 2, 2020, a second ATM from May 8, 2020 to June 30, 2020, and a third ATM announced on November 6, 2020. The ATM offerings ultimately raised $52.6 million of proceeds pursuant to their ATM offerings. In each of Spectrum's ATM offering prospectuses, Defendants explained that they would use the funds raised to pay for "general corporate purposes, including, without limitation, research and development and clinical development costs to support the advancement of our in-development drug candidates, activities in connection with the launch of our in-development drug candidates." In each instance, Defendants were motivated to inflate Spectrum's stock price in the lead up to and during the ATM offerings in order to ensure a fruitful financing for the Company.

279. Additionally, before the market opened on July 30, 2020, Spectrum announced the pricing of an underwritten public offering of 21,666,667 shares of Spectrum common stock at a public offering price of $3.00 per share. The offering price seemed to investors like a discount off the prior day's closing price of $3.88 per share, although investors did not know that the price was

inflated by Defendants' fraud. The timing of this offering was suspicious because by early July 2020, Defendants had access to the results from Cohort 3, which showed that the cohort did not meet its endpoint. Instead of sharing this adverse information with the market, however, Defendants proceeded with the public offering in late July 2020. This financial machination also had its intended effect: the Company reaped approximately $61.1 million in net proceeds from the offering.

280. All told, Spectrum raised $113.7 million in cash through this series of dilutive offerings. These funds acted as a lifeline for the struggling company that still had not brought either of its pipeline products to market. Defendants' decision to raise this much-needed capital through a series of opportunistic ATM offerings and another public offering provided them a motive to inflate the price of Spectrum common stock because, but for Defendants' materially false and misleading statements regarding the status of the Rolontis BLA and the Pozi trials, Spectrum's Class Period stock price would have been substantially lower.

G. Defendants' Misstatements Were Close in Time to the Corrective Disclosures

281. As late as October 2, 2019, Lebel assured investors the changes Spectrum made to the ZENITH20 trial – compared to the MD Anderson trial – including the way its clinical sites managed adverse effects, should "play in [Spectrum's] favor." Remarkably, two months later before the market opened on December 26, 2019, the Company shocked investors by reporting that Pozi did not meet its pre-specified endpoint in Cohort 1.

282. Similarly, on the Company's Q3 2020 Earnings Call on November 4, 2020, Turgeon stated: "I'm really confident in our ability to meet our corporate objectives and advance our programs with the aspiration of bringing new treatments to the patients with cancer who need it." Then, less than seven weeks later on December 22, 2020, Defendants reported that Cohort 3 had also failed. CW-2 explained this was a misleading impression, because "[i]t was the understanding when I left [in Q3 2020]" within Spectrum that Pozi would not be approved by the FDA due to the intolerable side effects and their impact on efficacy. CW-2 added that "companies present things in the best possible light and commit errors of omission." As an example, he/she said Spectrum "didn't

mention about the side effects and the dosage issues. If you're only reporting positive things, you lead analysts and investors to think the drug is positive and will get approved."

283. The temporal proximity of Defendants' misstatements regarding the FDA's inspection of the Hanmi facility in South Korea and the disclosures similarly indicates Defendants' scienter. Leading up to the FDA's inspection of the manufacturing plant, Defendants repeatedly expressed their confidence in gaining approval of their BLA. As late as May 13, 2021, Lebel told investors: "***[W]e remain confident that our preparation with our partner Hanmi, should result in a positive outcome for this FDA plant inspection***." Only three months later, on August 5, 2021, Spectrum announced that the CRL from the FDA "cited deficiencies related to manufacturing and indicated that a reinspection [of the Company's manufacturing facility] will be necessary." CW-2 explained that Spectrum executives "sent inspectors to Hanmi to do mock inspections," but Hanmi "failed [the mock inspections] a couple of times." This was because "the quality of plants and people [at Hanmi] were not up to industry standards." CW-2 said it was "common knowledge" at Spectrum that Hanmi failed its mock inspections. Accordingly, the timing of the Company's disclosures and confidential witness accounts that directly contradict the substance of Defendants' statements also support a strong inference of scienter.

H. Corporate Scienter

284. The allegations above also establish a strong inference that Spectrum as an entity acted with corporate scienter throughout the Class Period, as the Individual Defendants, Spectrum's officers, management, and agents, had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and to disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were made knowingly or recklessly, and without a reasonable basis, for the purpose and effect of concealing the truth from the investing public. By concealing these material facts from investors, Spectrum maintained and/or increased its artificially inflated common stock prices throughout the Class Period.

VIII. LOSS CAUSATION

285. During the Class Period, Defendants made materially false and misleading statements by misrepresenting the status of Spectrum's developmental drugs Pozi and Rolontis. They misled the market about Pozi's efficacy, safety, and ability to compete with other cancer drugs and misleadingly described their efforts to prepare the Rolontis manufacturing facility for inspection by the FDA. Defendants' material misrepresentations and omissions artificially inflated the price of Spectrum common stock and operated as a fraud or deceit on members of the Class. Later, as the true facts were revealed, the price of Spectrum common stock fell significantly, as the prior artificial inflation came out of the stock price over time. As a result of their purchases of Spectrum common stock during the Class Period, Plaintiff and other Class members suffered economic loss, *i.e.*, damages, under the federal securities laws.

286. After the market closed on December 19, 2018, Spectrum announced that based on a subset of data from MD Anderson's ongoing Phase 2 clinical trial, the FDA did not grant BTD status to Pozi for the treatment of patients with metastatic NSCLC with EGFR exon 20 mutations. Investors also learned that, according to "the FDA's guidance on BTD, in the absence of target specific control, the efficacy of poziotinib in patients with mutations had to be compared to non-mutation specific non-small cell lung cancer patients." And that, "[b]ased on published data," the best existing therapy was "combination chemotherapy with VEGF inhibitor with an objective response rate of 22.9%."

287. As a direct result of the disclosures on December 19, 2018, Spectrum's stock price significantly declined. The price of Spectrum common stock dropped from a December 19, 2018 closing price of $10.44 per share to a December 20, 2018 closing price of $6.39 per share – a decline of 38.8% on high volume of 6,786,893 shares. In comparison, on the same date, the Russell 2000 Index declined only 1.7% and Spectrum's peer index declined 3.1%.[12]

[12] The peer index cited above is based on the Company's 2019 SEC Form 10-K, and is comprised of publicly traded companies Spectrum identified as peers, including ACADIA Pharmaceuticals, Aerie Pharmaceuticals, Amicus Therapeutics, Clovis Oncology, Corcept Therapeutics, Eagle Pharmaceuticals, Halozyme Therapeutics, Heron Therapeutics, Intercept Pharmaceuticals, Ironwood Pharmaceuticals, Lexicon Pharmaceuticals, Omeros, Pacira Pharmaceuticals, PTC Therapeutics, Repligen, Retrophin, Supernus Pharmaceuticals, Theravance Biopharma and Vanda

288. Analysts attributed the decline to the market's surprise about Pozi's failure to obtain BTD status and new information concerning the appropriate comparator, though the market still held out hope for the future of the drug. On December 20, 2018, a Jeffries analyst wrote: "We are a bit surprised FDA did not grant BTD to pozi in EGFR exon 20 NSCLC given its impressive ORR and durability vs. current options." And an analyst from Guggenheim wrote: "Given the absence of an active control, it appears that the FDA elected to compare vs. data from an unselected patient population where response rates with chemotherapy and an anti-VEGF may be as high as ~23% and a PFS of ~4-5 months. In our view, an ORR of 40% is still a substantial improvement as long as responses are durable."

289. Spectrum's stock price remained artificially inflated because Defendants continued to misrepresent and conceal information related to Pozi's response rates and performance in clinical trials and the status of the Rolontis BLA. Moreover, when announcing the FDA's decision to deny Pozi BTD status on December 19, 2018, the Company confirmed that its "overall development plan and timeline for a New Drug Application remains unchanged."

290. Before the market opened on December 26, 2019, Spectrum announced that Pozi did not meet its pre-specified endpoint in Cohort 1 of the Phase 2 clinical trial, ZENITH20. The confirmed ORR was only 14.8%. The Company also disclosed alarming statistics regarding the safety of the treatment: 34.9% of patients experienced Grade 3 skin rash, 17.5% experienced Grade 3 diarrhea, 9.5% experienced Grade 3 paronychia, and 7.9% experienced Grade 3 nausea. Spectrum's stock price cratered as a direct result of the disclosure. The price of Spectrum common stock declined from a December 24, 2019 closing price of $8.75 per share to a December 26, 2019 closing price of $3.50 per share – a decline of 60.0% on unusually high volume of 21,370,588 shares. In comparison, on December 26, 2019, the Russell 2000 Index stayed flat and Spectrum's peer index decreased 1.4%.

291. Market analysts attributed the drop directly to the surprisingly terrible efficacy results from the Cohort 1 Study. On December 26, 2019, a Guggenheim analyst wrote: "The overall

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Pharmaceuticals. (Luminex and Momenta excluded due to lack of trading data, did not trade during entire class period).

response rate (ORR) was only 15%, significantly below what we estimated would be necessary to support potential accelerated approval (*see* here). This significantly lowers our confidence in the drug's potential in other, still ongoing settings (*e.g.* Cohorts 2 and 3), consistent with a downside scenario highlighted previously." On the same date, a Cantor Fitzgerald analyst wrote: "We view this result as thesis changing since we believed poziotinib was the key value driver and after this result we are unsure of its efficacy."

292. But Spectrum's stock price remained artificially inflated because Defendants continued to misrepresent and conceal information related to Pozi's response rates and performance in clinical trials and the status of the Rolontis BLA. Investors continued to hold out hope for Cohort 3, with a Jeffries analyst noting on April 29, 2020 that "we believe the naive cohort 3 pop will indeed be healthier and more likely to better tolerate the original 16 mg QD dose."

293. After the market closed on December 22, 2020, the Company announced that "its pre-specified primary endpoint in its Phase 2 clinical trial, [ZENITH20], evaluating poziotinib in first-line NSCLC patients with EGFR exon 20 insertion mutations was not met in Cohort 3." The news caused Spectrum's stock to decline 9.1% on the disclosure regarding the Cohort 3 failure, closing on December 22, 2020 at $4.25 per share and closing on December 23, 2020 at $3.87 per share, with high trading volume of 3,050,914 shares. In comparison, on December 23, 2020, Russell 2000 Index increased 0.9% and Spectrum's peer index increased 0.1%.

294. Analysts attributed the stock price decline to the Cohort 3 results. On December 23, 2020, a Cantor Fitzgerald analyst wrote: "We assign the poziotinib EGFR exon 20 insertion mutation opportunity a 0% POS, given both cohorts have not met the primary endpoint."

295. Artificial inflation related to the statements and omissions concerning the Rolontis manufacturing facilities remained in the stock until the announcement of the Rolontis CRL on August 6, 2021. Before the market opened on August 6, 2021, the Company disclosed that it received a CRL from the FDA regarding its BLA for Rolontis. According to the news release, "[t]he CRL cited deficiencies related to manufacturing and indicated that a reinspection will be necessary." Spectrum common stock dropped from an August 5, 2021 closing price of $3.25 per share to an August 6, 2021 closing price of $2.55 per share – a decline of 21.5% on high volume of 18,689,859

shares. In comparison, on August 6, 2021, the Russell 2000 Index increased 0.5% and Spectrum's peer index decreased just 0.6%.

296. Analysts attributed the stock price drop to the unexpected news concerning the FDA's CRL for Rolontis based on the failed inspection of the Hanmi facility that did not conform to Spectrum's BLA. On August 6, 2021, a Guggenheim analyst wrote: "This news is disappointing, especially in context of a previously withdrawn BLA filing in March 2019 due to manufacturing issues as well as mgmt's prior commentary on additional preparations for pre-approval inspection and potential commercial launch."

297. The declines in Spectrum's stock price on December 20, 2018, December 26, 2019, December 23, 2020, and August 6, 2021 were a direct result of the nature and extent of Defendants' prior misstatements and omissions being revealed to investors and the market. The timing and magnitude of Spectrum's stock price declines negate any inference that the losses suffered by Plaintiff and other members of the Class were caused by changed market conditions, macroeconomic, or industry factors, or by Company-specific factors unrelated to Defendants' misrepresentations. Instead, the economic losses suffered by Plaintiff and other members of the Class were a direct result of Defendants' misrepresentations that inflated Spectrum's stock price and the subsequent decline in the value of the stock when the misrepresentations and omissions were revealed.

IX. NO SAFE HARBOR

298. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances do not apply to any of the false and misleading statements pleaded in this pleading. None of the statements complained of herein was a forward-looking statement. Rather, they were historical statements or statements of purportedly current facts and conditions at the time the statements were made, including statements about data and information that Spectrum had access to.

299. Spectrum's "Safe Harbor" warnings accompanying its forward-looking statements issued during the Class Period were ineffective to shield those statements from liability because they were not accompanied by meaningful cautionary language. Given the then-existing facts

contradicting Defendants' statements, any generalized risk disclosures made by Spectrum were not sufficient to insulate Defendants from liability for their materially false and misleading statements.

300. Defendants are also liable for any false or misleading forward-looking statements pleaded because, at the time each forward-looking statement was made, the speaker knew the statement was false or misleading and was authorized and/or approved by an executive officer of Spectrum who knew that the forward-looking statement was false.

X. SPECTRUM SECURITIES TRADED IN AN EFFICIENT MARKET

301. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Spectrum common stock traded in an efficient market, was liquid and traded with moderate to heavy trading volume during the Class Period;
- the Company's stock was traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and
- Plaintiff and members of the Class purchased, acquired, and/or sold Spectrum common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

302. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

303. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed herein.

XI. CLASS ACTION ALLEGATIONS

304. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of the Class, consisting of all those who purchased or otherwise acquired Spectrum common stock during the Class Period and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are the Individual Defendants and their immediate families, the officers and directors of the Company, at all relevant times, and members of their immediate families, legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

305. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Spectrum common stock was actively traded on the NASDAQ in an efficient market. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Spectrum or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

306. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

307. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

308. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented or omitted material facts about the business, operations, and management of Spectrum;
- whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- whether the price of Spectrum common stock during the Class Period was artificially inflated because of Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

309. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I
For Violations of Section 10(b) of the Exchange Act
Against All Defendants

310. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

311. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

312. Such conduct was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members as alleged herein; (ii) artificially inflate and maintain the market price of Spectrum common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Spectrum common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

313. Pursuant to the above plan, scheme, conspiracy, and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases, and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Spectrum common stock. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Spectrum's business practices.

314. By virtue of their positions at Spectrum, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each of the Defendants knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

315. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Spectrum, the Individual Defendants had knowledge of the details of Spectrum's internal affairs.

316. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Spectrum. As officers and/or directors of a publicly held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Spectrum's business practices. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of Spectrum common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Spectrum's business and financial

condition that were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Spectrum common stock at artificially inflated prices and relied upon the price of the stock, the integrity of the market for the stock and/or upon statements disseminated by Defendants, and were damaged thereby.

317. During the Class Period, Spectrum common stock traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Spectrum common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Spectrum common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Spectrum common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and the other Class members.

318. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, violated §10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder.

319. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's stock during the Class Period, upon the disclosure of the facts alleged herein.

COUNT II
For Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

320. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

321. During the Class Period, the Individual Defendants participated in the operation and management of Spectrum, and conducted and participated, directly and indirectly, in the conduct of

Spectrum's business affairs. Because of their senior positions, they knew the adverse non-public information about Spectrum's business practices.

322. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Spectrum's financial condition and results of operations, and to correct promptly any public statements issued by Spectrum which had become materially false or misleading.

323. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, and public filings that Spectrum disseminated in the marketplace during the Class Period concerning Spectrum's results and operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Spectrum to engage in the wrongful acts complained of herein. Spectrum, in turn, controlled the Individual Defendants and all of its employees. The Individual Defendants, therefore, were "controlling persons" within the meaning of §20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged that artificially inflated the market price of Spectrum common stock.

324. By reason of the above conduct, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act.

COUNT III
For Violations of Section 20A of the Exchange Act
Against the Individual Defendants

325. Plaintiff repeats and re-alleges each and every allegation set forth above as if fully set forth herein.

326. As detailed herein, the Individual Defendants were in possession of material non-public information concerning Spectrum. The Individual Defendants took advantage of their possession of material non-public information regarding Spectrum to obtain significant insider trading profits during the Class Period.

327. The Individual Defendants' sales of Spectrum common stock (set forth below and in the attached Appendix E) were made contemporaneously with Plaintiff's purchases of Spectrum common stock (set forth below and in Plaintiff's certification (Exhibit A) during the Class Period.

328. Turgeon made the following sales of Spectrum common stock contemporaneously with the following Plaintiff purchases of Spectrum common stock:

Turgeon Sales			Plaintiff Purchases		
Date	Amount	Price	Date	Amount	Price
01/11/2019	36,311	$10.87	01/14/2019	10,000	$10.60
01/16/2019	5,091	$10.44	01/17/2019	10,000	$10.52
05/16/2019	22,702	$8.53	05/16/2019	7,000	$8.43
			05/17/2020	2,000	$8.17
11/18/2020	162,473	$4.13	11/18/2020	9,600	$4.14
01/19/2021	3,844	$3.81	01/26/2021	10,000	$3.96
01/20/2021	3,889	$4.31			

329. Gustafson made the following sales of Spectrum common stock contemporaneously with the following Plaintiff purchases of common stock:

Gustafson Sales			Plaintiff Purchases		
Date	Amount	Price	Date	Amount	Price
01/11/2019	33,692	$10.87	01/14/2019	10,000	$10.60
01/16/2019	3,207	$10.44	01/17/2019	10,000	$10.52
01/19/2021	2,582	$3.81	01/26/2021	10,000	$3.96

330. Lebel made the following sales of Spectrum common stock contemporaneously with the following Plaintiff purchases of common stock:

Lebel Sales			Plaintiff Purchases		
Date	Amount	Price	Date	Amount	Price
06/22/2020	5,474	$3.16	06/22/2020	10,000	$3.11
06/23/2020	4,167	$3.35	06/26/2020	5,000	$3.01
06/22/2021	5,821	$4.09	06/22/2021	10,000	$3.98

331. Riga made the following sales of Spectrum common stock contemporaneously with the following Plaintiff purchases of common stock:

Riga Sales			Plaintiff Purchases		
Date	Amount	Price	Date	Amount	Price
01/16/2019	10,499	$10.44	01/17/2019	10,000	$10.52
04/2/2019	1,882	$10.57	04/09/2019	5,000	$10.35
05/14/2019	2,388	$8.82	05/15/2019	1,000	$8.50
			05/16/2019	7,000	$8.43
			05/17/2019	2,000	$8.17
05/13/2020	2,086	$3.25	05/13/2020	8,000	$3.10
			05/13/2020	1,700	$3.08
			05/13/2020	300	$3.08
			05/13/2020	1,000	$3.10
			05/13/2020	142	$3.10
05/14/2020	1,125	$3.06	05/14/2020	7,716	$3.04
01/19/2021	64,626	$4.00	01/26/2021	10,000	$3.96

01/19/2021	11,657	$3.81			
01/20/2021	10,000	$4.31			

332. Plaintiff and members of the Class who purchased shares of Spectrum common stock contemporaneously with sales by the Individual Defendants suffered damages because: (1) in reliance on the integrity of the market, they paid artificially inflated prices as a result of the violations of §§10(b) and 20(a) of the Exchange Act as alleged herein; and (2) they would not have purchased the securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by the false and misleading statements and concealment alleged herein.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

DATED: March 29, 2024

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APPENDIX A

Blue boxes=Efficacy of Existing Treatments
Green boxes=Target for FDA Approval
Red boxes=Baseless Optimism

Pozi MD Anderson Timeline

March 2017:
MD Anderson launched. Defendants know > 43% target for BTD and 22.9% comparator from FDA.

March 6, 2018: Turgeon: There is ***"limited activity in these mutations from existing TKIs"***

May 3, 2018: Turgeon: ***"Current therapies only have less than 10%*** *- I think a 6% to 10% response rate"*

May 16, 2018: Turgeon: ***"current TKIs and other therapies only have a 6% to 8% response rate"***

May 16, 2018: Turgeon: ***"I know as a drug developer, if I can get a 20% to 30% response rate, I can get a drug approved"***

August 9, 2018: Q2 2018 Results: Riga: "***current available treatments is less than 10%***"

September 24, 2018: Trial ends – 43% ORR shown. Defendants know BTD target not met.

3-month period where defendants know BTD standard not met

November 8, 2018, Riga: *"we remain **very steadfast** in our belief that there is an unmet need, and poziotinib is showing indications of being **substantially better** than currently available treatments"*

November 8, 2018: Riga: "In *the EGFR cohort, there was a 43% confirmed objective response rate in the evaluable population.* ***This compares favorably to an overall response rate of less than 10% with available TKIs"***

Dec 19, 2018: Investors learn BTD denied

3/1/2018 4/1/2018 5/1/2018 6/1/2018 7/1/2018 8/1/2018 9/1/2018 10/1/2018 11/1/2018 12/1/2018 1/1/2019

APPENDIX B

Purple boxes=Outdated Results
Orange boxes=Adverse Events
Red boxes=Baseless Optimism

Pozi ZENITH20 Cohort 1 Timeline

October 2017: ZENITH20 Cohort 1 begins. Target of 30% ORR known.

May 16, 2019 & June 6, 2019
Turgeon sold over 40,000 shares for nearly $340,000 in proceeds

Between 3/25/19 and 4/1/19,
Gustafson sold over 15,000 shares for nearly $159,000 in proceeds

August 8, 2019: Riga: *"**we feel really strong about** . . . **the data readout in Q4 and is well ahead** in the development life cycle with poziotinib"*

October 2, 2019: Lebel: Pozi ***"has shown a response rate of 43% or so"***

October 2, 2019: Lebel: *modifications to the study relative to MD Anderson **"should play in our favor"***

October 2, 2019: Turgeon: *"**it's nice to be in a pole position** and we certainly are because we have two fully enrolled trials and – where **others are just getting started**"*

October 2, 2019: Lebel: Decision to prophylax every patient against diarrhea "***should play in our favor***"

September 11, 2019: Turgeon: *"**[MD Anderson]** . . . **showed a 43% overall response rate,** which was much higher than anything"*

March 10, 2019: Spectrum has fully confirmed results showing that Pozi did not meet ORR endpoint

9-month period where defendants know that Cohort 1 has failed

December 26, 2019 –
Final results announced ORR 14.8%

April 5, 2019 – March 2, 2020: First ATM offering

11/1/2018 12/1/2018 1/1/2019 2/1/2019 3/1/2019 4/1/2019 5/1/2019 6/1/2019 7/1/2019 8/1/2019 9/1/2019 10/1/2019 11/1/2019 12/1/2019 1/1/2020 2/1/2020 3/1/2020

APPENDIX C

Red boxes=Baseless Optimism
Orange boxes=Adverse Events

Pozi ZENITH20 Cohort 3 Timeline

May 9, 2019: ZENITH20 Cohort 3 starts enrollment, target of >30% ORR known to defendants.

May 7, 2020: Lebel: *"we believe on the basis of the data and modeling we've done that* ***we could mitigate the amount of adverse events we see****"*

July 7, 2020: Lebel: ***"Cohort 3 could behave differently."***

November 4, 2020: Turgeon: *"I'm* ***really confident*** *in our ability to meet our corporate objectives and advance our programs"*

November 4, 2020: Lebel: ***"Clearly, we monitor safety on all our studies,*** *including these cohorts and for signals that would be out of the ordinary"*

Nov. 18, 2020: Turgeon sold **162,473 shares** for $671,013. **24%** of Turgeon's holdings

Dec. 14, 2020: Gustafson sold **25,696 shares** for $128,480. **7%** of his holdings

Dec. 16, 2020, Turgeon sold **150,899 more shares for** $709,225**, 29%** of his remaining holdings

July 4, 2020: Spectrum has fully confirmed results showing that Pozi did not meet ORR endpoint

5.5-month period where defendants know that Cohort 3 has failed

Final results announced on 12/22/20 ORR 27.8%

5/8/20 – 6/30/20: Second ATM offering

July 30, 2020: Spectrum launched public offering

November 6, 2020: Third ATM offering

4/1/2020 4/8/2020 4/15/2020 4/22/2020 4/29/2020 5/6/2020 5/13/2020 5/20/2020 5/27/2020 6/3/2020 6/10/2020 6/17/2020 6/24/2020 7/1/2020 7/8/2020 7/15/2020 7/22/2020 7/29/2020 8/5/2020 8/12/2020 8/19/2020 8/26/2020 9/2/2020 9/9/2020 9/16/2020 9/23/2020 9/30/2020 10/7/2020 10/14/20... 10/21/20... 10/28/20... 11/4/2020 11/11/20... 11/18/20... 11/25/20... 12/2/2020 12/9/2020 12/16/20... 12/23/20... 12/30/20...

APPENDIX D

Rolontis Site Inspection Timeline

Q3 2020: CW-2 leaves Spectrum. As of this date, Spectrum had failed multiple mock inspections.

Nov. 4, 2020 – **Lebel:** *"On the manufacturing side,* ***we have conducted multiple mock inspections"***

Nov. 4, 2020 – Turgeon: *"And I can tell you,* ***we have Spectrum boots on ground there. . . . We have outside experts we've hired to run these – not only run these mock inspections, but also help the readiness. . . . They do this – they know exactly what people – what the FDA is looking for an inspection."***

Dec. 22. 2020 – Turgeon: *"The facility has been through* ***multiple mock inspections****.* ***It's kind of like the army now*** *is what I say, we're still* ***going through the drill on a weekly basis****, still doing the mock inspections, getting ready for any questions we might get.* ***We have Spectrum people on the ground at the plant."***

March 16, 2021: Spectrum announced Hanmi inspection

Between 3/15/21 and 3/16/21 All Defendants make substantial insider sales

March 30, 2021: Lebel: *"We and our partner, Hanmi, are* ***ready*** *for the FDA pre-approval plant inspection that has been scheduled for May."*

May 13, 2021: Turgeon: *"Hanmi's world-class facility is* ***ready for this inspection."***

May 13, 2021: Lebel: *"we remain confident that our preparation with our partner Hanmi, should result in a positive outcome for this FDA plant inspection."*

May 8, 2020- June 30, 2020: Second ATM offering

July 30, 2020: Spectrum launched public offering

Nov. 6, 2020: Third ATM offering

5/25/2021
FDA Inspects Site

3/1/2020 4/1/2020 5/1/2020 6/1/2020 7/1/2020 8/1/2020 9/1/2020 10/1/2020 11/1/2020 12/1/2020 1/1/2021 2/1/2021 3/1/2021 4/1/2021 5/1/2021 6/1/2021

APPENDIX E

Individual Defendants' Trades

Gustafson, Kurt A.			
Transaction Date	Price	Shares Sold	Proceeds
3/22/2018	$18.13	2,640	$47,863
3/26/2018	$17.38	1,300	$22,594
3/28/2018	$16.35	4,350	$71,123
1/11/2019	$10.87	33,692	$366,232
1/16/2019	$10.44	3,207	$33,481
3/25/2019	$9.46	3,797	$35,920
3/26/2019	$9.90	926	$9,167
3/29/2019	$10.65	5,974	$63,623
4/1/2019	$10.73	3,000	$32,190
4/1/2019	$10.81	1,642	$17,750
1/16/2020	$3.37	2,522	$8,499
1/17/2020	$3.33	1,621	$5,398
2/19/2020	$2.77	4,733	$13,110
2/20/2020	$2.85	3,333	$9,499
3/31/2020	$2.31	4,326	$9,993
4/1/2020	$2.23	3,135	$6,991
12/14/2020	$5.00	25,696	$128,480
1/19/2021	$3.81	2,582	$9,837
1/20/2021	$4.31	1,944	$8,379
2/19/2021	$3.64	4,672	$17,006
2/22/2021	$3.73	4,000	$14,920
3/15/2021	$3.63	20,365	$73,925
3/16/2021	$3.69	16,318	$60,213
Total		**155,775**	**$1,066,194**

Lebel, Francois			
Transaction Date	Price	Shares Sold	Proceeds
11/6/2019	$8.16	6,963	$56,818
4/2/2020	$2.17	1,228	$2,665
4/3/2020	$2.18	854	$1,862
6/22/2020	$3.16	5,474	$17,298
6/23/2020	$3.35	4,167	$13,959
11/6/2020	$3.50	7,025	$24,588
11/9/2020	$3.56	5,000	$17,800
3/15/2021	$3.63	22,631	$82,151
3/16/2021	$3.69	18,828	$69,475
4/5/2021	$3.31	1,125	$3,724
4/6/2021	$3.24	1,025	$3,321
6/22/2021	$4.09	5,821	$23,808

6/23/2021	$4.00	5,000	$20,000
Total		**85,141**	**$337,468**

Riga, Thomas J.			
Transaction Date	Price	Shares Sold	Proceeds
3/26/2018	$17.41	220	$3,830
4/2/2018	$15.58	1,948	$30,350
4/16/2018	$18.60	3,900	$72,540
4/17/2018	$19.07	1,840	$35,089
5/14/2018	$18.10	3,290	$59,549
6/25/2018	$18.76	235	$4,409
1/16/2019	$10.44	10,499	$109,610
2/20/2019	$11.47	2,285	$26,209
4/2/2019	$10.57	1,882	$19,893
4/11/2019	$10.75	16,493	$177,300
5/14/2019	$8.82	2,388	$21,062
1/16/2020	$3.37	11,381	$38,354
1/17/2020	$3.26	5,000	$16,300
2/19/2020	$2.77	5,085	$14,085
2/20/2020	$2.85	2,500	$7,125
3/31/2020	$2.31	1,854	$4,283
4/1/2020	$2.23	938	$2,092
5/13/2020	$3.25	2,086	$6,780
5/14/2020	$3.06	1,125	$3,443
1/19/2021	$4.00	64,626	$258,504
1/19/2021	$3.81	11,657	$44,413
1/20/2021	$4.31	10,000	$43,100
2/19/2021	$3.64	5,018	$18,266
2/22/2021	$3.73	5,000	$18,650
3/15/2021	$3.63	23,291	$84,546
3/16/2021	$3.69	18,828	$69,475
5/13/2021	$3.09	3,402	$10,512
5/14/2021	$3.07	2,250	$6,908
Total		**219,021**	**$1,206,675**

Turgeon, Joseph W.			
Transaction Date	Price	Shares Sold	Proceeds
3/22/2018	$18.17	3,100	$56,327
3/28/2018	$16.40	4,810	$78,884
4/17/2018	$19.00	11,565	$219,735
1/11/2019	$10.87	36,311	$394,701

1/16/2019	$10.44	5,091	$53,150
3/25/2019	$9.46	5,315	$50,280
3/29/2019	$10.65	6,307	$67,170
5/16/2019	$8.53	22,702	$193,648
6/6/2019	$7.95	18,240	$145,008
1/16/2020	$3.37	3,753	$12,648
1/17/2020	$3.33	1,944	$6,474
2/19/2020	$2.77	6,262	$17,346
2/20/2020	$2.85	3,750	$10,688
3/31/2020	$2.31	4,059	$9,376
4/1/2020	$2.23	2,502	$5,579
11/18/2020	$4.13	162,473	$671,013
12/16/2020	$4.70	150,899	$709,225
1/19/2021	$3.81	3,844	$14,646
1/20/2021	$4.31	3,889	$16,762
2/19/2021	$3.64	7,257	$26,415
2/22/2021	$3.73	7,500	$27,975
3/15/2021	$3.63	40,091	$145,530
3/16/2021	$3.69	28,243	$104,217
Total		**539,907**	**$3,036,796**